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Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ◉ No
- ○ Unsure

A.2 Please give the reasons you formed this view.

The tests are invasive; apart from the possibility that such tests can introduce additional infections, they are also the sorts of tests that people would refuse if they were advised there was no medical benefit to their being tested in that way. If recruitment is to take place during dialysis sessions, however, there is a possibility subjects are sufficiently able to express preference. It's a lower bar to the capacity test, but one which may suffice in ethical terms.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ◉ No
- ○ Unsure

B.2 Please give the reasons you formed this view.

There is absolutely no certainty that the research design, as expressed, is capable of generating the findings sought. Variables cannot be controlled, and analytical methods unsuitable for attempting their control.

B.3 What are your views about "delayed consent"?

Delayed consent is no consent. Consent must always be given prior to an event's occurrence if it is to be sought at all; beyond the damage to the construct of consent, there are dangers of coercion and implicit coercion.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ○ Yes
- ○ No
- ◉ Unsure

C.2 Please give the reasons you formed this view.

It's not clear whether participation could be halted if the patient was showing signs of distress or otherwise unwelcome effects. It's also not clear how frequently measurements would be taken (which would also provide an opportunity to identify whether a patient had regained sufficient capacity). I'm not sure it's possible to make a general decision here on the basis of the sketchy info.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

Any intervention that risks the life of a patient, whether immediately or downstream, must require explicit consent.

D.3 What are your views about the proposed “opt out” process?

An opt out process is entirely unsuitable, and dependent on too many uncontrolled factors (awareness raising), and requires particular action on the part of the entire possible population (wearing bracelets etc).

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

Too many uncertainties with the study design; as noted, even in the event of benefit, it would be short lived. Importantly, the idea that participants who cannot consent may show different effects to those who can is wrong footed: the capacity to consent construct is a legal one, not something inherent to any diagnosis.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

Large sectors of the disabled population are treated like the property of their 'caregivers' and family. Whilst it may be the case that many caregivers will always try to consider what they know or believe is a person's preference, they're often sold duds on the basis of 'best interests' considerations concocted by practitioners. Beyond this, there are major issues of vulnerability in this sector, and service users and their families can feel obligated to be 'helpful.' It's coercive and unsatisfactory.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes, but it very much depends on the nature of the research. Highly invasive research should not be conducted, irrespective of possible benefit.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

Study designs must be absolutely methodologically rigorous and subject to review not just by ethics panels (given the reality that many ethics panels are comprised of people who understand little or nothing of research). There must be absolutely no other way of getting the data. However, it's important to note that existing capacity provisions aren't particularly robust, and it seems likely that many people are able to make decisions that mean something to them without being 'assessed' as 'competent.' Preference may be a better bar.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

An apartheid system would be very troubling. There is a tendency for particular groups to be disenfranchised: those with mental illness diagnoses are treated as suspect; people with Downs syndrome viewed as property et cetera. Any disparities in the legislation would likely be exploited to further dehumanise and annex such people, with consequent erosion of the rights the CRPD is intended to protect.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Dissent is an expression of preference. I strongly believe that preference is a better bar than capacity; consequently, any dissent must be correspondingly respected.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- (•) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Delayed consent is no consent. The idea is that there is some research to which certain persons could be compulsorily subject. That seems a dangerous path to travel.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ( ) Yes

- ○ No
- ◉ Unsure

4.2 Please make any further comments you have about question 4.1.

There is a huge difference between 'vulnerable' groups and persons who lack capacity. In theory, there is no condition that necessarily excludes capacity, although in practice persistent disorders of consciousness and other such impairments mean that the only capacitous decisions are advance decisions. In addition, within a vulnerable group may be many individuals who are less vulnerable, and who certainly have capacity. All persons in a 'vulnerable group' may have capacity. Capacity is, however, a flawed concept. So this is an oddly worded question, really--hard to see how vulnerability and incompetence could be conflated. It's really disappointing.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ◉ No
- ○ Unsure

5.2 Please give reasons for your answer.

Utilitarianism becomes very problematic when it becomes an obligation on others indifferent to the wider good. Considerable erosions of liberty and autonomy here.

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

I do think ethics committee approval should be sought and obtained, but that is not, in itself, enough. Many people on ethics committees know nothing of research, the standard of proof required for different disciplines, what may or may not be generated--and nor do many of them care to know. As the case studies demonstrate, any methodological lack (or lack of info about methodology) can fundamentally alter the ethical considerations. Extra-agency peer reviews of methodology may be the only possible assurance.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

There needs to be an identifiable potential benefit to the participant. If possible, there should be an identifiable guaranteed benefit. Any potential harms should be absolutely minimal and very regularly screened for (at a higher rate than usual monitoring for similar effects). Potential harms should not be permanent, or invasive.

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

Less emphasis on caregivers and ethics committees.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where an EPOA or welfare Guardian is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where family or whanau is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

EPOAs.

Additional comment.

Also think that equal weight should not be given to all family members. Irrespective of legal status, a person's 'chosen' family members should be consulted over eg. parents, siblings if there is doubt or disagreement. This is particularly the case for persons with mental health conditions.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Participation in research should never be subject to judicial application. I'm aware that some lawyers believe a court can always decide on issues where capacity is thought to be absent, but there should be no compulsory participation in research.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 epoa
2 family
3 clinician/GP
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

the researcher should never be permitted to make an unconsulted decision. Ethics committees have a very limited role in determining the *sorts* of acceptable participants. The courts have no role here.

Final comments

9. Please add any final comments or suggestions you wish to make.

Your consultation rests on the idea that 'capacity' is an agreed concept and has meaning outside of the law. It doesn't. Be far better to align this approach with the CRPD emphasis on will and preference, so that preference is the bar rather than the assessment of capacity, which is flawed and foundering.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 1 March 2017 at 8:40am | Completed on 1 March 2017 at 9:33am

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You do not need to answer all of the questions for your responses to be considered by the Commissioner.

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The study

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Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ○ No
- ◉ Unsure

A.2 Please give the reasons you formed this view.

why collect information and not use it to inform the patients care? Then the information can be useful to the patient. What if they found as a result of the patient being in the study that a dose of antiobiotic was toxic?

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ◉ No
- ○ Unsure

B.2 Please give the reasons you formed this view.

They aren't asking if they would want it removed , that part is done. They are asking if their data is used. The first scenario at least had no change to treatment this one is much more vague.
Is it really neccesary to have this study done at all? If both of the products are safe and tested then why does the study have any merit?

B.3 What are your views about "delayed consent"?

I have no problem with delayed consent when there may be a direct benefit to the patient. I have signifcant problems with delayed consent when it involves an intervention and is not an observational study.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ○ Yes
- ◉ No
- ○ Unsure

C.2 Please give the reasons you formed this view.

The design of the study doesn't fill me with confidence that if I was distressed by additional contact that my enrolement would cease immediately. This assumes that I would want to have more contact and not less.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

this subject is too serious to be managed with a placebo. I would expect that an alternative hypothesis is that death at the time of cardiac arrest is even less when no adrenaline is used.

D.3 What are your views about the proposed “opt out” process?

we don't even have an opt out process for something as serious as organ donation. Why should people be asked to opt out of research when the enrolement occurs during a life threatening situation.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ○ No
- ◉ Unsure

E.2 Please give the reasons you formed this view.

it could benefit them directly. On the other hand it could cause them undesirable side effects that may be worse than if they didn't have downs.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ◉ Yes
- ○ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

the consultaion with family members is to ask if they think the patient would want to be enrolled and could tolerate the possible impact of being enrolled ie side effects and monitoring

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

if there is a benefit to them

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

if there is no benefit and only risk of harm then no. Whereas if there is possiblity of benefit and a small amount of harm then the possiblity the patient would have wanted to enrol if able to consent is high

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

if a person could be disabled by the research and they need to consent to the resaerch it must be under the remit of the HDC

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- ( ) No
- (•) Unsure

2.2 Please give reasons for your answer

some people may have been grimacing before enrolment.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Only if there was a possible benefit to the patient and the possible benefit was less than the likliehood of harm. ie obervational rather than interventional studies

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

wholeheartly agree.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ◉ No
- ○ Unsure

5.2 Please give reasons for your answer.

not if it interventions, when it is observational I am less bothered.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

it removes the need for good will

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- (•) Yes
- ( ) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

I think the benefit versus burden question rasies a element of good faith that the researcher is wanting to improve the experince of the particpant not merely understand science

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- ( ) No
- (•) Unsure

Additional comment.

I just don't think it should be up to doctors or researchers. I think their focus is too narrow.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where an EPOA or welfare Guardian is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

next of kin

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

I would expect the EPOA or welfare guardian to know what the consumer would want for themselves

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where family or whanau is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

The first option about all circumstances when whanu are available would have been my prefernce however it is the when available part that concerns me. The researcher may say they weren't here, hence they weren't available.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

they may be able to provide information about the consumer would want for themselves.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

it may be helpful to have as much insight as possible as to whether the person would have wanted to be enrolled. The issue is how well the person being consulted with knowns the person the researcher wants to enrol

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 1
2 2
3 3
4 4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

The researcher has an ulterior motive to enroll the person so they should have no say

Final comments

9. Please add any final comments or suggestions you wish to make.

I think the current guidance is correct and should not be altered. Who does it really benefit?
We have such stringent rules because it protects a person's right to decide could erode that. Doctors have too much influence now over what is deemed in the best interests of consumers. Please don't give them any more freedom to do that

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 1 March 2017 at 9:58am | Completed on 1 March 2017 at 10:50am

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

If doctors don't already know the answer then they need to do experiments to find out. If this improves treatment for people after me then this is fine. After all I'm only getting the 'best' treatment because of people before me.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Yes. Otherwise people who have medical problems that mean they can't consent will never get the advantage of being in studies or receive best treatment.

B.3 What are your views about "delayed consent"?

If people designing the studies have permission from ethics groups then I am happy they can decide what is best as long as they talk to my family who can represent me. Even if my family were not available I would be happy

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

People with dementia have the same right as everyone else to find medicines that may make them better. Otherwise any illness that affects your ability to make decisions will never be studied and patients who are unfortunate enough to suffer from them will never have the chance everyone else does.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (•) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

Everything we know is only because of what other people have had done to them. We do not know if adrenaline causes harm but, as you say, it has been given for 50 years. How has it been allowed to continue for so long? The issue is why this hasn't already been resolved (after 50 years!), not whether people should or shouldn't be studied without consent.

D.3 What are your views about the proposed “opt out” process?

If it is thought to be in the public interest (and, as before, ethics groups think it is fine) then opt out is not required, in my mind. A public information campaign will a) not cover everyone (visitors from out of town) and b) cost money that should be spent on the study for patient benefit.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- (●) Yes
- ( ) No
- ( ) Unsure

E.2 Please give the reasons you formed this view.

Because patients with Downs have as much right as anyone else to benefit from studies. Not including them in studies is discrimination.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- (●) Yes
- ( ) No
- ( ) Unsure

E.4 Please give the reasons you formed this view.

Family must always be listened to but they are not the patient (unless they have legal rights). They may not represent the patients views and may be as biased as they accuse the doctors of being!

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes because some types of patients may never be able to give consent but would benefit from these studies. They should not be excluded from the benefit of both being in the study and the knowledge that is then gained to help these types of patients.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

Every study should be considered by a group of ethics experts that include medical, legal and patient advocates. If they agree, and the study is closely monitored, then I have no problem with this. I presume this is what already happens.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (●) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

If its good enough for healthcare providers, it should also apply to academics. No-one should be exempt. The code of rights is far ranging and protects many people.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- ( ) No
- (●) Unsure

2.2 Please give reasons for your answer

Dissent, as with consent, must be informed. If dissent is not informed then it is irrelevant (as uninformed consent would be). It should be decided if the person is making that decision with all the knowledge at hand by people who have expertise in this area.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (●) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

See previous answers. Such patient should not be excluded from the benefits of research that will help both them and then others.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ( ) Yes

- (●) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

This may be difficult to prove and highlights the difference between what is ethical & what is legal. Ethical permission should be enough.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- (●) Yes
- ( ) No
- ( ) Unsure

5.2 Please give reasons for your answer.

Because every medical treatment we use is only allowed because it was shown to benefit someone else. We know what we know because of others. This is the nature of our society.

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ( ) Yes
- (●) No
- ( ) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

The ethics group are more likely to represent the patient than the researcher and able to see both sides.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- (•) Yes
- ( ) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- (•) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

The patients has decided the EPOA represents their wishes legally so they should be consulted if time is available to do so

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ◉ No
- ○ Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where family or whanau is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Unless the patients has specifically appointed a family member to represent them if they are not able to make decisions (with an EPOA) then they should not represent the patient. Their views may differ & this may not be clear when they speak 'for the patient'

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☑ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

They should be informed but not asked to provide consent if they have no EPOA

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ◉ No
- ○ Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where a provider not involved in the research is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

The chance for consultation is during the ethics process not when putting the patient in the study

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA
2
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 1 March 2017 at 12:04pm | Completed on 1 March 2017 at 3:16pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

1. It is very important to study the sickest patients in the hospital so that we can learn how best to look after them.
2. Minimal risk to participation.
3. Societal benefits of participation clearly outweigh any risk.
4. The patient themselves may benefit from the knowledge gained in this study (if they are admitted to an intensive care in the future).

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

1. The options here are to allow pseudorandom practice (i.e. random a essential random choice based on idiosyncratic preferences of the doctor) and to learn nothing or to systematically study these products and learn which is actually better.
2. Currently, if a clinical trial were not occurring, Dr B would be highly unlikely to mention to the patients that these two options even existed if a trial were not to occur because they could reasonably be regarded as equivalent. It is highly illogical to say that pseudorandom practice based on idiosyncracities of what products are available in particular hospitals without consent is acceptable but systematic evaluation of such differences is not.
3. I would not want the opportunity to learn from my illness to be wasted
4. Given that participating in this trial would appear to have no risks compared to standard care I consider that it would be reasonable to proceed without any form of consent and to then have the opportunity to opt-out of use of my personal health information in the study at a later time

B.3 What are your views about "delayed consent"?

I think that delayed consent would be fine; however, I consider that a simple information leaflet that provided information about this trial along the opportunity to 'opt out' of use of heath data would be more appropriate.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

1. If we do not study patients with dementia we will not be able to improve their care
2. The study involves minimal risk and from the description the benefits of the new knowledge gained outweigh the potential risks
3. Excluding the patients with dementia who are not competent will mean that the trial results will not apply to them. As a consequence, it is vitally important that they are included in the study so that they can potentially benefit from its findings.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (•) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

1. If we do not study the sickest patients we will not be able to improve their care.
2. The scenario describes a position of equipoise (ie. adrenaline might result in either better or worse outcomes than placebo); consequently, participating in this trial represents an effective way to 'hedge one's bets'.
3. The benefits or conducting a trial of this nature clearly outweigh the risks and the collateral benefits to society far outweigh any potential or perceived threat to individual patient autonomy.

D.3 What are your views about the proposed “opt out” process?

The proposed opt-out process is completely impractical. The public information campaign would be prohibitively expensive and, if this were the only acceptable approach, would effectively make conducting research of this type impossible in New Zealand. Provision of information to patients when / if they recover along with an opportunity to opt out of use of their health information if they choose would make more sense.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating

suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ○ No
- ◉ Unsure

E.2 Please give the reasons you formed this view.

On the basis of the information provided it is difficult to form a view as to the relative risks vs. benefits of what is proposed. However, if an ethics committee reviewed the background information supporting the hypothesis and considered that there was a reasonable basis for the belief that the treatment being tested might improve cognition in patients with Down's I think that the research should be able to be conducted. Excluding incompetent patients in this situation means they lose the benefits of participation. Moreover, one would presume that if the treatment was demonstrated to be acceptable it would potentially become available for patients in the future.

For me, the key issue is whether an ethics committee considers that the potential risks are sufficiently small that the benefits of allowing the trial to occur outweigh the risks.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ◉ Yes
- ○ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

I consider that family / whanau / caregivers would be well-placed to weigh up the pros and cons of trial participation.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes. If we cannot study the sickest patients in the hospital, we cannot learn how to care for them best.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

In the case of ICU research we are considering research in the sickest patients in the hospital. Such research is vital for the health of New Zealanders. Every barrier to conducting such trials will delay acquisition of knowledge and potentially patients will die as a result. In my view, we need a legal framework that allows ethics committees to consider the best approach to use for the unique circumstances of each individual clinical trial. Sometimes this will be fully informed consent prior to trial enrollment before the patient becomes unwell; sometimes it will be consent from a family member prior to enrollment; sometimes it will be provision of information and the opportunity to opt out of participation or to opt out of use of a patient's information once competence is recovered.

Overall, I believe it is important that we have a system that appropriately balances the rights of individual patients to autonomy and the societal benefits that result from studying the sickest patients in our hospitals in order to improve their care.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (●) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

The same law should apply to all; however, it is very important that the law is sufficiently flexible that it does not dogmatically restrict the conduct of ethically improved research. There is no reason why research that can legally proceed in nearly every developed country in the world should be considered illegal in New Zealand.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- ( ) No
- (●) Unsure

2.2 Please give reasons for your answer

It depends on how the law were to be drafted. Interpreting whether such expressions represent dissent or not may be extremely difficult and would be highly subjective. In general, though, an incompetent patient should be encouraged to express their views whenever possible and their views should be considered.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- ( ) No
- (●) Unsure

3.2 Please give reasons for your answer.

It is not possible to decline something that has already occurred. A more appropriate framework is enrolment without consent followed by consent for ongoing participation and / or use of private health information once competence has been recovered. However, if this is what is being evisaged then absolutely it should be able to occur.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ○ Yes
- ◉ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

There is no reason for this guideline to be enshrined in law. The law should simply state that all clinical research (both observational and interventional) must be approved by a recognised ethics committee. Codifying aspects of ethical guidelines is unnecessary.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

This is the fundamental reason why such research is important. If we do not study incompetent patients, we cannot be expected to improve their care.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ◉ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	approved by an ethics c
2	potential benefits from l
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

The ethics review process provides an appropriate framework for considering whether or not a trial should be allowed to occur and the most appropriate framework for informed consent for each circumstance.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

1. the risks of participation should be small and not disproportional to the potential benefits in terms of knowledge gained
2. the study should be approved by an ethics committee

7.3 Please state the reasons you formed this view.

If we do not study incompetent patients we cannot improve their care.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? *Please select all that should apply, or provide comment below if you prefer.*

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. *(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)*

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Families should be consulted and should be involved.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

In the ICU setting, independent clinicians would generally not be available.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [x] Other

Additional comment.

Consideration of potential risks and benefits of participation for the individual patient.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

Please specify who.

Clinicians involved in research who have expertise in both research and clinical medicine. These people generally have the best understanding of the potential risks and benefits of participation.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

☑ In all cases where this person is available?

☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)

☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?

☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

☐ Consulted by decision-maker

☐ Power to veto consumer's participation in the research

☐ Provide or withhold consent on behalf of the consumer

☐ Other

Additional comment.

Where enrolment is considered appropriate this person should consult with family members as soon as it is practical and reasonable to do so.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1
2
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

It depends on the individual circumstances of the study. In my view, we need a legal framework that allows ethics committees to consider the best approach to use for the unique circumstances of each individual clinical trial. Sometimes this will be fully informed consent prior to trial enrollment before the patient becomes unwell; sometimes it will be consent from a family member prior to enrollment; sometimes it will be provision of information and the opportunity to opt out of participation

or to opt out of use of a patient's information.

It would be highly undesirable for the law to be proscriptive in relation to ethically improved research that has the potential to save lives and improve outcomes where the approach to informed consent is considered reasonable and appropriate by an ethics committee

Final comments

9. Please add any final comments or suggestions you wish to make.

No additional comments

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 1 March 2017 at 3:59pm | Completed on 1 March 2017 at 5:05pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

a) There is no change in treatment envisaged whether the patient is in the programme or not;
b) Data from urine and blood tests could provide valuable information for future treatments;
c) Routine urine and blood tests would be being carried out on such a patient anyway.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

a) With random selection of the product used in any particular situation, there is no violation of the patient by invasion or the introduction of another element into the surgery.
b) One or other product is routinely used already and the research is simply to compare the two in order to ascertain which is more reliable and effective.
c) It is not as if the original surgery would be undone to implant the other product in the end.

B.3 What are your views about "delayed consent"?

That very much depends on what the consent is asked for. In this instance, personally I cannot see any problem with it, but I realise that many people are hypersensitive to any information about themselves or their treatment being shared with anyone.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ( ) Yes
- ( ) No
- (•) Unsure

C.2 Please give the reasons you formed this view.

a) I am unsure how the 'quality of life' would be assessed.
b) I am also doubtful as to just how one would go about obtaining consent under these circumstances. Even someone supposedly rational might have difficulty in appreciating the object of the exercise.
c) What is the measure of 'severe dementia'?

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

a) I might be the one who received the salt water!
b) The body of evidence does not support the research as yet.
c) Of course, if I am dead, there is no answer to the dilemma because it might not have been the adrenaline which caused by departure.

D.3 What are your views about the proposed “opt out” process?

At what stage would you ask someone whether or not he/she wanted to take part in the research?
A heart attack does not usually pre-warn the its imminent arrival or severity, and by the time it strikes, the patient could well be unconscious anyway.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

a) The desired benefits to the patient have not been proved.
b) The possibility of suicidal thought following administration of the drug.
c) The fact that the drug would not be available following the research period.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

a) No family member is able to know absolutely what the person concerned, if fully cognitive and 'normal', would choose.
b) Family would be imposing on the Down Syndrome person their own perception of the advantages/disadvantages of the drug to the person.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes. As in the first two case studies, there are times when an unconscious patient's response to a particular treatment can provide valuable information for future treatment of the condition.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

a) There should be no invasion of the person by physical means.
b) There should be no change in treatment just to provide answers - only results should be assessed.
c) Lessons from the 'Unfortunate Experiment' should be kept in mind.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Purely academic research smells of the 'Unfortunate Experiment'. If anything it should be under more stringent conditions than those applying to health care or disability services providers.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

You never know just how much a person who appears to be unconscious hears and understands. If there is any possibility that the person is uncomfortable with the proposed treament/research programme, it should definitely not be carried out.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- ( ) No
- (•) Unsure

3.2 Please give reasons for your answer.

It is too easy retrospectively to presume the patient has consented. After all, the research has already been done, so there is precious little the patient can do about it.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

a) I wonder what research which is proposed on incompetent patients could not actually be done on competent people.
b) If the research cannot be carried out on competent persons, it seems like using the incompetent as guinea pigs.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ◉ No
- ○ Unsure

5.2 Please give reasons for your answer.

a) It is using the person as a guinea pig.
b) The criterion as it stands is 'in the patient's best interests' - in this case, it would be for other people's best interest.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

a) Given the human propensity to push the boundaries, it would be all too tempting to assume that the proposed research is in the patient's best interest.
b) There has to be sound ethical control of all such ventures.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

a) If the researcher is the one making the decision that participation is in the best interests of the patient, this is patently open to abuse. Of course, the researcher would think that.
b) The researcher would have to be able to prove the advantage 'beyond reasonable doubt'.
c) The definition of 'advantage' and 'disadvantage' would need to be clearly set out.

7.3 Please state the reasons you formed this view.

a) Being of advanced years, I have seen too much of the ways human beings with an axe to grind can skew information to bolster up their theories so they can get permission/approval for their schemes.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- (•) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☐ Consulted by decision-maker
- ☑ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where family or whanau is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☑ Power to veto consumer's participation in the research
- ☑ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ◉ No
- ○ Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where a provider not involved in the research is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ○ Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where this person is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA or welfare guardi
2 Provider not involved in
3 Family/whānau
4 Researcher
5 Other

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

This is a very contentious issue and I would probably have to ponder it for some time yet, but in general I would err mostly on the side of incompetent patients not being involved in research without consent. The exceptions would be Case Studies 1 & 2.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 2 March 2017 at 9:26am | Completed on 2 March 2017 at 10:57am

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

I would want the other patients that come after me to be able to benefit from this knowledge

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

As potentially i as a patient would have either of the products, based on the individual surgeon preferences, i think it is reasonable to have a trial that may show that one product is better than the other, or they may have same effectiveness but the price different. I would want for NZ to benefit from the knowledge gained by my surgery and treatment. Also i know that patients in trials get better follow up, so i would benefit from that regardless of the product outcomes.

B.3 What are your views about "delayed consent"?

I think delayed consent is acceptable, as i would not be able to give consent prior to surgery and it would be the only way i can be enrolled in this trial.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

I would take part, again there is a strong likelihood of improving the standard of care plus extra attention is always beneficial.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an "opt-out" process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with "NO STUDY" engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

Also, "no study" bracelet is too broad, as i may be quite happy to take part during my ICU or CCU stay, but no in this particular study.
I would support a study in this patient group that would be observational to see if one can collect evidence that adrenaline is harmful in CPR(large sample size, as i presume that previous studies did not reach statistical significance), but not an active study like this. Once you die, you die and there is no "fixing "option if NS did not work. The time is too precious during CPR and there is no significant evidence to suggest that adrenaline is harmful or that we have a better option

D.3 What are your views about the proposed "opt out" process?

The opt out option presumes that the honours are on the participant to decline, but in this case it is not practical/possible as we don't know when we will go in cardiac arrest, and therefore not many people will wear the bracelet.
In general, the opt out option acceptable in some of the studies, but not in this one.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary

because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- (•) Yes
- ( ) No
- ( ) Unsure

E.2 Please give the reasons you formed this view.

As in your scenario, the effect the drug has on healthy volunteers may be different to effect it has on the Down patients. So if we want to improve the outcomes in people with the Down syndrome, we need to do clinical trials in this population.
I would have concerns if the study medication would not be available to participants that have benefited from the study treatment, so this is one thing that would need to be addressed. Also, if the study sponsor would not be willing to provide the medication after the trail for participants that shown improvement on the study treatment, i would not enroll either my child or suggest enrollment to my family member

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ( ) Yes
- (•) No
- ( ) Unsure

E.4 Please give the reasons you formed this view.

I would expect researcher to make an effort and discuss the study with potential participants as well. Some of the Down patient have higher level of functionality and they should be consulted about the study like that. In fact majority will be able to give some opinion on the study if presented in appropriate manner

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes, i do. If we are not able to do research in clinical areas that have patients that are unable to give consent, we will not be able to improve the treatments and outcomes.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

The research in this patient group has to be tightly controlled and all project should reviewed by the HDEC as this patient group would come under vulnerable population. I also think that researchers will need to be trained or show evidence of training that allows for research to be conducted in this patient group. For example, i would not have great confidence nor would be comfortable for this type of research to be conducted by the junior researcher.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (●) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

As per my comment above, i think we need to have specific definition of what is considerate vulnerable population – the one we have currently is too broad and open for interpretation. Otherwise i think the process will need to be the same, with extra questions and considerations by HDEc that are already in place when applications submitted in this patient group.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- ( ) No
- (●) Unsure

2.2 Please give reasons for your answer

I think that it would be difficult to judge if participant is expressing fear or anxiety that is related to research in this group. If this introduced, it would need to be clearly defined and that is very difficult. I would think that in any case scenario if patient is unhappy with the study participation in any way, they should be able to withdraw, it is their right to do so. So i am undecided on this one as it would be open for interpretation and then can be misinterpreted.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (●) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

i think it is fair that once the person is able to give consent, they are asked if they want information collected so far to be part of the study or if they have objections. The consent discussion does also helps with patient understanding what is the trial about and potential risks/benefits of taking part.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes
- ( ) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

I think it should be a requirement to show evidence that you have to do a clinical trial on this patient group and you can't get same results in other patient groups. We have to also remember that regulatory bodies such as Medsafe will require evidence that the medication/device /treatment is effective in this particular patient group, not in healthy volunteers or some other patient groups.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- (•) Yes
- ( ) No
- ( ) Unsure

5.2 Please give reasons for your answer.

I think it is important to us as humans that even if we may not get benefit, somebody else may be cured in the future or have better outcomes. This is what the clinical trials are about, to make things better for patients and caregivers

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- (•) Yes
- ( ) No
- ( ) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	should be people with
2	limited previous eviden
3	
4	
5	

Any others?

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

As per Good Clinical Research Practice guidelines, any research that should have ethical approval. Also any research that involves vulnerable population must be approved by the HDEC (Health and Disability Ethics Committee) as per ethical guidelines, and i believe it is fair and reasonable.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- (•) Yes
- ( ) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes

- (•) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where family or whanau is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)

- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA or welfare guardi
2 Researcher
3 Family/whānau
4 Provider not involved in
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Depending on the type of the study, the ranking of decision making can be different, for example in ICU based study, the researcher would be very high on the decision making ladder; where in dementia type trial POA and family would rank higher.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

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Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

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Started on 2 March 2017 at 4:09pm | Completed on 2 March 2017 at 4:58pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

There is no other way for this potentially important knowledge be gained.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Assuming ethics committee has reviewed trial process.

B.3 What are your views about "delayed consent"?

Absolutely necessary if medical science is to progress.
Preferable to studies being done in countries without such consent processes

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

I would expect information to be given to my next of kin and the research to have ethics committee approval ie to be properly conducted.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (•) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

large amounts of medical practice are not based on good scientific trials. Many such treatments have been found to be non-beneficial or harmful when subjected to rigourous scientific process.

D.3 What are your views about the proposed “opt out” process?

Where there is equipoise ie it is genuinely uncertain what the risk/benefit is, the opt out seems entirely appropriate.
If someone wants to insist on an unproven treatment, I guess they can request this.Who pays and when is it reasonable to decline a request for unproven treatments are interesting questions.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- (●) Yes
- ( ) No
- ( ) Unsure

E.2 Please give the reasons you formed this view.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- (●) Yes
- ( ) No
- ( ) Unsure

E.4 Please give the reasons you formed this view.

Combined with ethis committee approval

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes.
Otherwise we are unable to improve care and outcomes for these patients

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

Approved by ethics committee as worthwhile trial/question, and scientifically conducted.
Next of kin informed as soon as practicable.
Opt out option when competent

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- ( ) No
- (•) Unsure

3.2 Please give reasons for your answer.

Seems not possible to give retrospective consent, but information to continue and use data prospectively important

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ( ) Yes

- ○ No
- ◉ Unsure

4.2 Please make any further comments you have about question 4.1.

there may be different treatment risks and benefits in vul vs non vul, so may have to research on vulnerable persons to get answers

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ◉ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Generally this will provide safeguard for society and ensure 'stupid research not undertaken

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

Must be a rational benefit that an Ethics committtee believes worthwhile

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- (•) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

If EPOA not immediately available the enrolment ok with EPOA informed ASAP.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
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Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where this person is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
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Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
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- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1
2
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

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Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

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Started on 6 March 2017 at 3:37pm | Completed on 6 March 2017 at 4:03pm

Health and disability research involving adult participants who are unable to provide informed consent

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In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

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The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

In this case, the consent could be given on my behalf by my spouse or children or my legal represantative

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

In this case, the consent could be given on my behalf by my spouse or children or my legal represantative

B.3 What are your views about "delayed consent"?

Possible

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

In this case, the consent could be given on my behalf by my spouse or children or my legal represantative

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (•) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

In this case, the consent could be given on my behalf by my spouse or children or my legal represantative

D.3 What are your views about the proposed “opt out” process?

Agree

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- (●) Yes
- ( ) No
- ( ) Unsure

E.2 Please give the reasons you formed this view.

In this case, the consent could be given on my behalf by my spouse or children or my legal represantative

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- (●) Yes
- ( ) No
- ( ) Unsure

E.4 Please give the reasons you formed this view.

We should give a best shot for any potentially effective and safe intervention

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes, a research should be allowed to proceed with adult participants who are unable to provide informed consent.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

In this case, the consent could be sought from next of kin or legal represantative of the patient.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Provided that the intervention under research is reasonably safe and may be superior to other available interventions or no intervention at all.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- (•) No
- ( ) Unsure

2.2 Please give reasons for your answer

Unless there are significant mental issues or other health conditions masking the patient's response

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Because it is in interest of the patients

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

From the public good perspective, this should be allowed

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ◉ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	Same health condition
2	Similar age
3	Similar sex
4	Similar ethnicity
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

As any clinical research, this should follow the Good Clinical Practice Guidelines

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- (•) Yes
- ( ) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

As in any other clinical research

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

Please specify who.

Next of kin or legal representative

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Family/whanau
2 Legal representative
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

The time is right to make these changes ASAP

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recomm

Started on 7 March 2017 at 3:00pm | Completed on 7 March 2017 at 4:59pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

My treatment would be standard and unaffected. The additional testing involved would not be detrimental and might be performed on samples already being obtained.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Both closure products are indicated and licensed for use in this situation. There is no known advantage of one over the other (there is equipoise).

B.3 What are your views about "delayed consent"?

No objection.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

The new regime might be beneficial and is unlikely to cause harm. Monitoring for harm would occur as part of the interaction.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an "opt-out" process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with "NO STUDY" engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (•) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

The evidence for benefit from adrenaline is unsupported and it might cause harm or adversely affect survival. There is no clear evidence either way. Historical treatment needs to be challenged.

D.3 What are your views about the proposed "opt out" process?

This is good in theory but rescuers need to be able to find the opt-out bracelet immediately and the patients need to be prepared to wear it, perhaps for a long time.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- (●) Yes
- ( ) No
- ( ) Unsure

E.2 Please give the reasons you formed this view.

I think that involvement of caregivers is important as they will be able to balance the small risk involved in taking the drug. These patients are usually well supervised so any suicide risk should be controlled and there is no evidence that Downs syndrome patients are affected similarly by the drug anyway.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- (●) Yes
- ( ) No
- ( ) Unsure

E.4 Please give the reasons you formed this view.

They will be very close to the patient and will historically have his/her interest at heart. There might need to be an exclusion if the patient is lacking in support and there is documented concern.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes. This is the only way of studying interventions intended to help critical patients. There need to be clear safeguards (non-maleficence) but the principle is important.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

The study should ideally demonstrate equipoise or evidence of benefit which needs to be assessed. It should not involve invasive treatments unless these are potentially lifesaving. Retrospective consent would help to provide patient feedback.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

The risk here is that the patient will become combative and if the treatment is continued, it could represent an assault on the patient.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- ( ) No
- (•) Unsure

3.2 Please give reasons for your answer.

Delayed consent would provide patient feedback helpful to the study but the intervention would have been made already.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ( ) Yes

- (●) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

It might be appropriate to undertake the research on both groups simultaneously, and in the case of critical illness, the research may be inappropriate for otherwise healthy patients.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- (●) Yes
- ( ) No
- ( ) Unsure

5.2 Please give reasons for your answer.

The statement implies equipoise for the participant. Benefit to others would be an additional advantage.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ( ) Yes
- (●) No
- ( ) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

I thought this was normal practice.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

Equipoise with potential benefit.
No evidence of harm from phase 1 or any other studies.

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

I believe that the HDEC and Ethics Committees should be involved in all cases as a matter of law. This appears not to be the case. Without their approval, the study should not proceed.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

I do not think that EPOA's or welfare guardians should necessarily have the final say as they are not independent. However, their views do need to be taken into account.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

My comment is the same as for EPOA's.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

The clinician could appeal to the HDEC or Ethics Committee if necessary.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 HDEC/Ethics
2 EPOA
3 family
4 GP or clinician
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 8 March 2017 at 3:58pm | Completed on 8 March 2017 at 4:53pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

The cost (pain of needles or catheter for urine sample) does not seem overly high. If the venous access was very difficult and patient was in a lot of pain then I dont think it would be appropriate to include them in the study, but if it is minor then it seems like a small cost for the potential benefits for future patients. It wont help them directly (unless they were to get sepsis in future) but could help other patients in the future. unlikely to remember pain of needle anyway or do any long term damage so i dont think it is that unethical.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

It does not negatively affect patients at all to be involved in this study. If the data is anonymised afterwards it does no harm to the patient, if there is a later followup that they dont consent to that is a different thing and they can decline that. We already observe what happens to patients in an informal way, documenting it more formally shouldnt always require the consent of the patient, especially if we are not giving them a controversial treatment/withholding standard treatment.

B.3 What are your views about "delayed consent"?

Makes sense to gain consent whenever possible although if they are not affected in any way and its anonymised, i think the data should be allowed to be included in the study.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

There may be a benefit to the treatment, it is only short term study, so if it is worse it will be for a shorter time, could provide valuable info that helps all dementia patients including the participant. If you are in control group you are getting normal care so it is also ok. I think most people with dementia would like to have more research to find out what is the best support for ppl w dementia

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ○ No
- ◉ Unsure

D.2 Please give the reasons you formed this view.

This case is more difficult since the outcome is mortality.
It is always hard when something is the standard and to question the standard. It is a very important research topic to find out the answer. If it was done it would need to be a small as possible pilot which would be reviewed and practice changed as soon as answer is found. Other types of study would be more ideal.Maybe the outcome for arrests are so poor that adrenaline or not is negliable difference on individual scale and more important on population level. Tricky one.

D.3 What are your views about the proposed “opt out” process?

It would be hard to have a fully informed public about the opt out bracelet and uptake would be low, even though more people would probably opt out if they could. Opt out would be good for something like organ donors though, as there is more benefit.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- (●) Yes
- ( ) No
- ( ) Unsure

E.2 Please give the reasons you formed this view.

if the family also consents and they must be aware of the possible side effect of suicide contemplation. They could watch the patient more closely during this time
There is a possible benefit for the patient and their carers.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- (●) Yes
- ( ) No
- ( ) Unsure

E.4 Please give the reasons you formed this view.

most whanau care about the patient enough to make a good decision, if there was any concern about them not providing good care for the patient they should not be carers for them.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

yes.
The possible benefits to the community with the condition (other sufferers as well as the patient suffering)

We should remember that our current treatments may also be doing just as much harm as the proposed study treatments and shouldnt let things get too stuck in stone because of dogma. Need to do research to ensure we harm patients less in future.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

-If they delayed consent and dont want to participate further that should be respected. (although if data anonymised and no follow up needed it should be allowed to be included).

-No long lasting damage expected
-no excessively painful treatments
-to stop study or cross over as soon as it is suggested

The possible harms
Whether the patient will experience pain or distress being involved in the study, if not, it should be allowed

Family should be aware of the study in some circumstances and sometimes be able to withdraw consent.

The research needs to be in areas that are very very uncertain

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (●) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- (●) No
- ( ) Unsure

2.2 Please give reasons for your answer

Depends on how long or consistent the refusal is, it should be repetitive refusal as labile moods may mean refusal once on a whim but mostly agree. Depends on how long the uncomfortable procedure goes on for as well. Needs to be a certain threshold for this to be enough to warrant stopping

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (●) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

yes definately, we need that data and it will help patients, i imagine most people would be in agreement. Maybe a study would be good to see if most people would retrospectively agree to being in the research. If it is high it should be changed.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ○ Yes
- ◉ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Depends what it is. Vulnerable groups dont necessarily suffer more than non-vuln. I dont think a law would help here. It should be at discretion and case by case basis, reviewed by ethics committee.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

Utilitarianism.
It may benefit them in the future or people in their community with similar. I think most people tend to be passionate about their condition and advocate for others with the same condition and would want advancement in treatment if possible.

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ◉ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

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Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

i think its always good to have ethics committee oversight if possible as they mght think of things that researcher hasnt thought of and recommend changes

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

-possible benefit of answering study (eg. If it will change management and decrease mortality this is more important than a study looking at measuring a biochemical test that may not correlate to clinical improvement)
-possible harm of being in study- both the treatment and the increase in blood tests etc
-look at if they have previously wanted to be a donor, prev research, opinions,

7.3 Please state the reasons you formed this view.

it would also be harmful to neglect research in disabled people because of the consent issue and then have no progress in the management of their diseases.

most people when able want to help others, especially those with same condition as them. many are unlikely to be able to recall suffering when acutely ill or if demented.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes

- ○ No
- ◉ Unsure

- ○ Yes
- ○ No
- ◉ Unsure

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

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rt to play in deciding whether an incompetent consumer is enrolled in a study?

- ◉ Yes
- ○ No
- ○ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☑ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

clinician looking after them.
Nurses will have input into the level of distress patient has as well and can feed that back to clinician.

Additional comment.

If they have grave concerns they should be able to withdraw, however the primary decision maker will be clinician.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☑ Consulted by decision-maker
- ☑ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer

☐ Other

Additional comment.

need to be able to veto, or else family may become very very aggrieved and this will harm scientific community.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

◉ Yes

○ No

○ Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

☑ In all cases where family or whanau is available?

☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)

☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?

☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

as per epoa, their input may be very valuable opinion should be gained but the clinician should be able to do the consent for the patient based on all info gathered. family could still veto it if really disagree

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

☑ Consulted by decision-maker

☑ Power to veto consumer's participation in the research

☐ Provide or withhold consent on behalf of the consumer

☐ Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

◉ Yes

○ No

- ○ Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☑ In all cases where a provider not involved in the research is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

may help to make that decision if they know patient well and what patient would want the extra info could be helpful

in hospital clinician to make final call

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☑ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where this person is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?

☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

☐ Consulted by decision-maker

☐ Power to veto consumer's participation in the research

☐ Provide or withhold consent on behalf of the consumer

☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 clinician
2 researcher
3 epoa
4 whanau
5

8.5 Please provide any other comments you wish to make about the decision-makers.

more consultation is needed if it is likely to make a big difference the the patients daily life or outcome

observational ones less so

Final comments

9. Please add any final comments or suggestions you wish to make.

should remember that we neglect research in the disabled and this isnt good so should try to strike a balance so research can help improve the lives and outcomes of those who cant advocate for themselves because if they could i am sure most would advocate for trying to improve things rather than staying stagnant

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 9 March 2017 at 2:35pm | Completed on 9 March 2017 at 3:40pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ○ No
- ◉ Unsure

A.2 Please give the reasons you formed this view.

If urine and blood was being collected for other reasons and they would just tack on a few extra diagnostic tests in the lab or I was already cathertirised and had an iv line in. The method of collecting the sample was already there. I would be ok with this.

However if I had to have an extra needle put into a vein for the blood sample and catheterised to give the urine sample. I would not be alorght with that.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Both drugs are already in use. This is effectively a clinical audit and could even be done potentially a retrospective analysis. If say for a period of 1 month they used one drug as an SOP and the next they uesed the other as an SOP.

B.3 What are your views about "delayed consent"?

I believe that delayed consent in this circumstance is perfectly reasonaable, especially as both products are clinically approved for use and are already in use clinically at the same time.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

From a very personal assesment and view. I would like to think that my participation in a study where by I could vastly improve the care of others in the future would be worth it. There appears to be no physical risk associated with this study and therefore I would personally be ok with it. It would be nice to think that you werent going through this expereince for nothing!

However I do think that if there is family available that could consent on behalf of the sufferer then they should be asked to consent on behalf of (Especially if they have medical power of attorney).

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ○ No
- ◉ Unsure

D.2 Please give the reasons you formed this view.

This particlar case study has made me feel quite uneasy. I guess becasu eboth options dont actually seem great. The idea that we have been using adrenalin for so long and it in itself is unproven, but the thought that I might receive saline in an event where something else could save my life makes me uneasy as well.

So I really and truly am unsure on this particular case.

D.3 What are your views about the proposed “opt out” process?

This is an incredibly risky method of obtaining effective consent. It would depend on so many variables. Area of recruitment, method of advertsising. You would have to be sure that the campaign reached everyone in the catchment area and then somehow ensure that everyone in that area was responding and making a decision in some way. Children included?

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

Not because I dont think that they should for research purposes, butthe fact that teh drug will not be available to them after the trial even it has shown benefit, is enough to say no. I would say no to this trial on this basis for participants who are abel to give consent.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ◉ Yes
- ○ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

If the above was different. I think that family/whanau would be able to make an informed decision for these types of pateints as they would be making those informed decsions for them in every other aspect of their life as well, if this was the case.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

yes I do believe research should in certain circumstances be allowed to proceed on adult participants who are unable to provide informed consent.
Life saving circumstances
No harm will come to the patient by participating in the research but could improve health outcomes for future sufferes.
For participants who ahve never in their life been able to make an informed decision for themselves and have always had a caregiver do this for them in every aspect of there living. I think caregivers should have the riogth to make an informed choice for them in regrads to research as well.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

If their is any potential harm to a participant - needs significant consideration.
Significant harm would need to be carefully defined.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

For these particpants they need there rights protected in research regardless of wether or not it is HDC related.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

This indicates that there is some level of cognitive awareness and therefore the patient potentially could make an informed choice for themselves. These levels again would need to be clearly defined not only based on the persons levle of cognitive awareness but also levels of expression and dissent.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes
- ( ) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ( ) Yes
- ( ) No
- (•) Unsure

5.2 Please give reasons for your answer.

Depends on teh level of potential harm

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ( ) Yes
- ( ) No
- ( ) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

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Any others?

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

This just seems like common sense.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- ( ) No
- (•) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- Yes
- No
- Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- Yes
- No
- Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- In all cases where an EPOA or welfare Guardian is available?
- Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- Consulted by decision-maker
- Power to veto consumer's participation in the research
- Provide or withhold consent on behalf of the consumer
- Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's

life or preventing serious damage to the consumer's health.)

- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Family
2 EPOA
3 Provider no involved in r
4 other
5 researcher

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 9 March 2017 at 8:41pm | Completed on 9 March 2017 at 10:02pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

Taking of blood tests constitutes a minimal risk of harm. There is significant capacity for future patients to benefit and there minimal risk.
That "there is little or no risk of harm" should replace "will benefit from" research. By it's nature, research intends to provide an answer to something which is not known. i.e. It is unlikely that a patient can described as directly benefitting from something which seeks to answer the question of what better practice actually is.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Provided that both closure products were current standard of care, it seems non-sensical to not compare the two in a head to head fashion to find out which is best.
The choice of which device the surgeon would use is (in clinical practice) usually up to the surgeon. It would likely not constitute part of the informed consent process anyway.

B.3 What are your views about "delayed consent"?

May be acceptable in circumstances where research cannot be practically conducted in patient who can give prospective consent. Should only be used where there are no reasonable alternatives where prospective consent can be sought.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

I would be prepared to participate because I think that the risk of harm is low, and acknowledge that there are no alternative patient groups: i.e. even if only those with mild dementia who are capable of consent were enrolled, it would still not answer the question of whether this treatment worked in those with more advanced disease (and presumably greatest potential to benefit)

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (•) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

I believe study participants get better care than those not enrolled in studies. This is a reasonable clinical question which cannot be answered in humans in an alternative way.

D.3 What are your views about the proposed “opt out” process?

The process of "opting out" via community information and then wearing a bracelet seems reasonably unlikely to constitute a meaningful decision, and I am unsure of its value.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

Given that there are some known potential harms from this treatment, I would advocate for prospective consent only. If the treatment were demonstrated as beneficial to patients with Downs syndrome who can consent, it may reasonable to perform another trial in those unable to consent

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ○ No
- ◉ Unsure

E.4 Please give the reasons you formed this view.

It probably does give reasonable protection, but cannot be regarded as equivalent to the individual themselves consenting

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes: it is impractical to expect research to automatically benefit the individual. By it's nature, research seeks to answer unknown questions to improve care in the future.
It is more reasonable to have a test of "no or minimal risk of harm"

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

There should be reasonable evidence of low to no risk to the individual.
There should be no equivalent patient groups who are able to provide consent.
Where there is some risk of harm, and there are no alternative patient groups, there should be a sufficient body of background evidence to suggest that the proposed change could reasonably be expected to have a good chance of benefitting the patient and evidence that the investigators have worked hard to minimise knowns risks of harm..

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- ○ Yes
- ○ No
- ◉ Unsure

1.4 Please make any general comments you have about question 1.3.

seems reasonable, but insufficient information has been provided as to why the is currently the case

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ○ Yes
- ○ No
- ◉ Unsure

2.2 Please give reasons for your answer

Incompetent individuals who are unable to communicate or understand by normal means are - by definition - likely to be misunderstood, and are also likely to be unable actually understand what they are participating in.

This should be contrasted to a competent patient who is unable to communicate by normal means - where non verbal signals of desire not to participate should clearly be respected.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ◉ Yes
- ○ No
- ○ Unsure

3.2 Please give reasons for your answer.

Acceptable, provided the standards for patients who are unable to give consent is initially met, or it reasonable to expect that the vast majority of patients would not object to the treatment proposed.
Where possible, the researcher should endeavour to understand the patients likely beliefs prior to research occurring.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ○ Yes

- ○ No
- ◉ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

yes, provided sufficient safeguards around minimising risk of harm are ensured and there are no competent alternative patient groups.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ◉ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- Yes
- No
- Unsure

6.2 Please give reasons for your answer.

Where research is proposed on a group of incapable patients, and that research is otherwise of a interventional type (e.g. audit or observational research) ethical approval would seem unnecessary.
There must be clear guidelines as to what constitutes research which does not require ethical committee approval, and it research which does not fit these criteria should require ethical committee approval.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- Yes
- No
- Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

) there should be minimal risk of harm from the proposed intervention, or
2) the research should compare accepted and current practices, or
3) there are no alternative patient groups who are able to consent, the research has reasonable capacity to benefit patients with this condition and the researcher has taken all reasonable measures to ensure that risks to the patient have been minimised.

Where practical, the researcher should have attempted to ascertain the likely wishes of the patient prior to commencing any research.

7.3 Please state the reasons you formed this view.

Many patients are incapacitated and there are no reasonable alternative patient groups.
Research has improved practice and continues to do so.
The HDC must strike a balance between protecting individual patients and ensuring research continues such that care of future patients can continue to improve.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- Yes
- No
- Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- Yes

- ○ No
- ◉ Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ◉ Yes
- ○ No
- ○ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where an EPOA or welfare Guardian is available?
- ☑ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Where and EPOA exists, that person has delegated authority to act in the persons best interests should the individual be incapacitated. Where they have been nominated, and there is time to seek their opinion, their consent should be regarded similarly to consent from the patient themselves

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☐ Consulted by decision-maker
- ☑ Power to veto consumer's participation in the research
- ☑ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Where there is no nominated EPOA, and there is sufficient time to seek opinion around the family/whanau's beliefs on the liklihood that the patient would wish to participate in this research should be sought. They should not offer consent, but if their insight indicates that the individual would likely object to participation, then research on that individual should not be performed.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)

- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ○ Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPO or guardian
2 Researcher
3 family/whanau
4 provider
5 other

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

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Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 9 March 2017 at 11:18am | Completed on 10 March 2017 at 9:55am

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

There is minimal risk of harm. Although there is no personal gain, research will contribute to improved understanding of treatment of this condition to the ultimate benefit of others

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Both treatments are currently clinically approved and therefore deemed safe and efficacious. Doctors always make pragmatic decisions on what treatments to apply to certain clinical situations where multiple options are available often based on little objective evidence. This study answers a legitimate question. There is no known risk of harm. Effectively, the doctor is consenting on behalf of the patient.

B.3 What are your views about "delayed consent"?

Delayed consent if appropriate in this situation. Research data should not be collected after consent is withdrawn. Data collected up to the time that consent is withdrawn should continue to be used.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ( ) Yes
- (•) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

This is a legitimate research question. Nevertheless, it is better that participants are able to provide informed consent (with support) where we are uncertain about risk of harm.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

If I understand this scenario correctly, true equipoise does not apply. We believe that current evidence still supports the use of adrenaline in cardiac arrest despite putative risk of harm. It is not ethical to administer placebo (no treatment) in this situation even with informed consent.

D.3 What are your views about the proposed “opt out” process?

This is impractical and unreasonable. It would never be possible to make contact with all those individuals in hospital or in the community that may suffer a cardiac arrest prior to the event.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

Risk/benefit equation for participants is heavily weighted towards risk (i.e. low mood contemplating suicide). Informed consent is required.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ◉ Yes
- ○ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

Proxy consent for family/whanau/caregivers is acceptable. This approach is not currently used in New Zealand, but it is used in other (overseas) domains with serious prejudice. We need to consider this approach more closely where legitimate research questions arise.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

I believe that research should be allowed to proceed with adult participants who are unable to provide consent. We need to be a more liberal in accepting proxy consent (family/whanau/caregivers).

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

There must be good science and a legitimate research question needs to apply with minimal perceived risk of harm from the intervention. The risk/benefit equation must be highly tilted in favour of benefit. This would bring us more in line with standard practice in Australia & the USA

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (●) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

A standard approach to health a disability research should apply whether this is a health-care provider or a non-provider

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- (●) No
- ( ) Unsure

2.2 Please give reasons for your answer

Our current practice is based in informed consent. If the subject is not deemed competent, any indication of dissent is not likely to be valid. It would be better to seek proxy consent in this situation

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (●) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Effectively the researcher is charged with weighing risk and benefit for the participant and making an informed consent on their behalf. That is acceptable.
It would be good if proxy consent from family/whanau/caregivers was also required if available.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (●) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Informed consent should apply where practicable

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

The whole purpose of clinical research is to improve our knowledge and ability to manage medical conditions that affect the whole community. Health care is funded from the public purse in New Zealand. It is reasonable that all patients should be expected to participate in clinical research provided that the researcher believes they will suffer no harm and proxy consent is obtained

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	Likelihood of harm sho
2	Potential benefit to the c
3	Proxy consent is availab
4	Research must have sc
5	Equipoise must apply
Any others?	HDEC approval is obtai

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (●) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Broad based review from independent ethics committee is fundamental to research on human subjects in the modern (post-Nuremberg) era. It is unthinkable that clinical research would be conducted without HDEC review

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (●) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

There must be sound scientific rationale for the research; there must be expectation of benefit (e.g. to the wider community); and there must minimal likelihood of harm to the participant

7.3 Please state the reasons you formed this view.

Clinical research is fundamental to the process of health quality improvement. We should look to remove barriers to research where we safely can. We should seek to align our standards with other domains of relevance to our health care system(e.g. the UK, Australia & the USA)

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (●) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (●) Yes
- ( ) No
- ( ) Unsure

Additional comment.

HDEC is often seen as a barrier to conduct of valid research in the clinical domain. This is really a post-Cartwright legacy and represents the pendulum swinging too far towards protectionism. We need to realign with our major research partners in the UK, Australia & the USA

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (●) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

(i) EPOA or welfare guardian
(ii) Family/whanau/caregiver
(iii) Responsible clinician in consultation with a second clinician
(iv) Family Court
(v) HDEC

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

EPOA for personal care and welfare gives the holder legal right to make health decisions on behalf of the subject. Participation in a research study is a health decision

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Family/whanau are important to the care of sick/incompetent patients. Sometimes, it takes longer to engage and obtain a collective decision from whanau. Nevertheless, the final decision is always going to be stronger with family/whanau involvement

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

EPOA and family/whanau/caregiver proxy consent should take precedence over provider not involved in research

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA or welfare guardi
2 Family/whanau/caregiv
3 Provider not involved in
4 Family Court
5 HDEC

8.5 Please provide any other comments you wish to make about the decision-makers.

Most research participation decisions for incompetent patient are made in the clinic or at the bedside. From a practical point of view, only first 3 decision-makers will be involved. In the rare situation where outside input is required and where a decision is not time-limited, it is reasonable to consult the court or to refer back to HDEC

Final comments

9. Please add any final comments or suggestions you wish to make.

This is a very long survey. Questions are quite testing (whoever put it together). I hope the output is productive and look forwards to feedback in due course

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Submission should NOT be considered as confidential for the purposes of this survey

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 13 March 2017 at 9:26am | Completed on 13 March 2017 at 10:17am

Health and disability research involving adult participants who are unable to provide informed consent

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In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

B.3 What are your views about "delayed consent"?

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

In this study there is potential for harm in those who receive placebo.

D.3 What are your views about the proposed “opt out” process?

I do not think it is practical - too difficult to implement

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

Potential for harm - the drug should be more thoroughly studied in consenting adults first

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes. As the law is worded virtually no research is possible, as most studies usually have no direct benefit to the participants- - unless, for example they receive an active drug that turns out to be effective and safe, which no-one can predict for certain. Even participants who are able to give consent often do not understand tha.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

I think the restriction should be that the study has low or no risk of causing harm; rather than that will benefit the participant.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- ( ) No
- (•) Unsure

2.2 Please give reasons for your answer

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

I think delayed consent is a bit irrelevant and pointless, unless the study involves ongoing assessments. In that situation it would be important that the patient gives consent for the rest of the study procedures.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ( ) Yes

- ○ No
- ◉ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ◉ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

The study should pose low risk or no risk to the participants

eg:
observational studies
Studies comparing treatments which are already part of standard practice where the optimal treatment is uncertain

7.3 Please state the reasons you formed this view.

the criterion of "benefit to the participant" almost never applies

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- ( ) No
- (•) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA or welfare guardi
2 Family/whānau
3 Provider not involved
4 Researcher
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

I think that the wording of the act is unsatisfactory for participants who can give consent as well as for those who cannot. In particular, I think it is rare that a study will have significant benefits for the participants themselves. The benefits are usually for society in general and in particular, other people with the same medical condition.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 13 March 2017 at 2:21pm | Completed on 13 March 2017 at 3:17pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

this is not a deviation from usual practice they are merely collecting data to investigate clearance of the antibiotic via dialysis. I think this poses no risk to the patient but will add to the body of evidence to influence future practice.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Both products are tested and in common use the data seeks to support which is the better option. I think enrolling in study and removing once able to consent if pt become capable to do so, is preferable option.

B.3 What are your views about "delayed consent"?

I think delayed consent is useful. It allows the organisation to commence protocol and not miss opportunities to enrol but if the patient removes decides it is something they would not wish to contribute to nothing is lost data can be omitted.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

I think as a healthcare professional I can see the potential benefit of undertaking research in this manner. The intervention may not benefit me but it would most certainly add tot he body of evidence to guide future service developments.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (•) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

we need to look at the efficacy of adrenaline in cardiac arrest. I think an opt out method of consent is not required.

D.3 What are your views about the proposed “opt out” process?

I think opt out methods can be useful in some instances, however opting out of a trial for cardiac arrest situations may not provide sufficient opportunity to do so.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

only those able to consent should be participants. This is because the effect will not be sustained once drug is ceased. There is evidence to suggest that the medication may increase contemplation of suicide in people without downs syndrome.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

I think family, whanau, caregivers may be consulted with the patient but they should not be asked to give assent for a trial enrolment.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

yes I think research may be able to proceed without consent. In cases specifically where there is minimal harm expected, i.e. testing an established therapy against another established therapy to determine best.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

In cases specifically where there is minimal harm expected, i.e. testing an established therapy against another established therapy to determine best.
I also think the case study with the adrenaline in cardiac arrest demonstrates another area where consent need not be sought. The current evidence suggests no benefit from continued use of adrenaline after initial dose so why has it not been investigated further. I guess I am trying to say why are we subjecting or patients to dogmatic practices when we can do a robust and measured trial to determine efficacy.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

one law make it easier for everyone to comply

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- ( ) No
- (•) Unsure

2.2 Please give reasons for your answer

I think once other avenues of facial expression are investigated. Are they saying no and they understand or are they grimacing because they are in pain and frightened? I can think of instances in ICU where no research would be done if we went off facial expressions alone.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

I'm thinking of the case study with the patients undergoing neurosurgery. Again the research would need to assess the treatment A against treatment B so long as both A & B had been shown to be of benefit.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

to safeguard against inappropriate studies on incompetent persons.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

because who is to say that the incompetent person may not have consented when they were competent (e.g. in dementia).
The patient population in the future may benefit from the research (that is the goal) and they (the incompetent person) may want to contribute to this.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ◉ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

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5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

definitely!
I think this will allow the researchers to identify and offer information on the rationale for the research and about the population under investigation.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- (•) Yes
- ( ) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

research is generally testing treatment A (standard care) with treatment B (new, hopefully improved - but has been tested in some format usually) so the participants are usually better off to be part of the trial.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where family or whanau is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

I think it should be in consultation with the potential participant, I also think a clause should be added to EPOA's!

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

I do not think any adult has the right to consent for another adult. I think they should be given the information to discuss with the potential participant but they should not be able to provide consent or veto.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

I think it may be reasonable to discuss with a GP or consultant not directly involved with research as they may have long-standing relationship with patient and be able to inform researchers on previous wishes of patient. They should not be able to consent or veto however.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 other - patient
2 EPOA or welfare guaidi
3 researcher
4 provider not involved in
5 family / whanau

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 13 March 2017 at 4:51pm | Completed on 13 March 2017 at 6:06pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

It would help others

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

It may benefit others

B.3 What are your views about "delayed consent"?

It may lead to anxiety for the patient and although may be part of "full disclosure" it is not really a form of consent. It would be better to seek consent from family members

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

May be of benefit to me and others

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

I think I would be more likely to die!

D.3 What are your views about the proposed “opt out” process?

It does not sound at all feasible. People should not have to wear bracelets to say they want standard treatment

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

It doesn't sound as if there is genuine uncertainty as to the drug's effectiveness - therefore unethical to trial it

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

Same as above

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes - where participants will not be harmed and there is genuine uncertainty as to the study question. If there is a high probability that study results will benefit patients

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

Family should be consulted for their consent if available. If there is any possibility of patient harm, should not be allowed. If a reasonable person is likely to object to being enrolled in the study it should not be allowed

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- ( ) No
- (•) Unsure

2.2 Please give reasons for your answer

For example in the ICU/dialysis question - patients may flinch when extra blood tests are being taken. Does this mean they withdraw from the study?

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- (•) No
- ( ) Unsure

3.2 Please give reasons for your answer.

It would cause anxiety and not benefit the patient if they said no

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

greater good!

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ◉ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

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Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

These patients are vulnerable

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- ( ) No
- (•) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

If the same had been tested in "normal" but comparable subjects

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- ( ) No
- (•) Unsure

Additional comment.

I am unsure what the laws are

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Doctors looking after the patient

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Provider
2 EPOA
3 Family
4 Researcher
5 Other

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

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Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

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Started on 14 March 2017 at 12:50pm | Completed on 14 March 2017 at 1:30pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

because it could benefit others.

B.3 What are your views about "delayed consent"?

I don't really like it as a concept because you are consenting after the fact. I think consent implies in advance so an alternative word would be more appropriate.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ( ) Yes
- (•) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

no a good enough argument in terms of harm minimisation.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

because I could be in a situation where I am not given adrenaline and need it.

D.3 What are your views about the proposed “opt out” process?

not sure how this could be implemented practically.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

unethical.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

because a good research process that protects vulnerable people requires more than just consultation with family.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

yes, because it may have an impact on improving the lives of disabled people.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

Where the researcher has established a proper process in terms of an ethical process in terms of research with vulnerable groups. With the involvement of disabled people themselves.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

because it is the right thing to do.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- (•) No
- ( ) Unsure

3.2 Please give reasons for your answer.

because I don't agree with it. It seems unethical to me.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ( ) Yes

- (●) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

because it might preclude disability research which is important.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ( ) Yes
- (●) No
- ( ) Unsure

5.2 Please give reasons for your answer.

because it seems unethical.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ( ) Yes
- ( ) No
- ( ) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Because this process ensures that the right processes are followed to protect the rights of the individual.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- (•) Yes
- ( ) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- ( ) No
- (•) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where an EPOA or welfare Guardian is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (●) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
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Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (●) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
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Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

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Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
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Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
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- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 epoa
2 family
3 researcher
4 provider
5 other

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

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Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

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Started on 14 March 2017 at 3:18pm | Completed on 14 March 2017 at 4:00pm

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In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

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You do not need to answer all of the questions for your responses to be considered by the Commissioner.

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The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

To me it is important that it is known how quickly the antibiotic is secreted. To maintain an appropriate level could be life saving.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

It is important to know which is the better product.

B.3 What are your views about "delayed consent"?

I'm sure that most would approve of the research. Delayed consent is important.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

As long as the study was stopped if the additional intervention was deleterious, I would be all for it.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ○ No
- ◉ Unsure

D.2 Please give the reasons you formed this view.

If it is a time honoured method of treatment, then surely if it is in use then there is a place for this. If the persons who happen to be receiving the salt and water die off faster, would the study be aborted?

D.3 What are your views about the proposed “opt out” process?

Not for me, but I am sure there would be others who would like that.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

If the drug is not available following the study, then it should not be used as a trial substance. The cost of this medication should be reviewed and discussions with PHARMAC held.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ◉ Yes
- ○ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

family/whānau/caregivers will look after the persons' best interests (hopefully).

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes. I would like my incapacity to benefit others.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

They should be non invasive, and not extend life for the benefit of the research.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

What is good enough for the goose, is good enough for the gander.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

If it is important enough to go through the hoops of obtaining consent, then the law should treat all persons equally.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

An important differentiation. In many of the case studies given this would not be possible.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

I believe this to be so.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ◉ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

All must be done to prevent Nazi style experimentation.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- (•) Yes
- ( ) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- ( ) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

What is an EPOA?

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where family or whanau is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

What I want and what my family in the situation into which they are thrust decide may be quite different.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☑ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ◉ Yes
- ○ No
- ○ Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where a provider not involved in the research is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 GP
2 Family/whanau
3 Researcher
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 17 March 2017 at 11:43am | Completed on 17 March 2017 at 12:42pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

It might help others in future. It doesn't affect my care. The blood and urine can be collected without my knowing

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

The research is comparing two usual treatments where it is not known which is superior. I am still getting a usual treatment. We should know which is better for future patients.

B.3 What are your views about "delayed consent"?

I would like to discuss the trial when I am capable. It is the best that can be done in the circumstances

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

There is a possibility of benefit. There may be some unwanted hassle. Again we should find out which treatment is superior

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ○ No
- ◉ Unsure

D.2 Please give the reasons you formed this view.

I am a doctor and researcher. I would want to see the scientific rationale in detail before agreeing. Adrenaline v no adrenaline seems extreme. Would adrenaline v lower dose adrenaline be a better first step. If no clinical difference or a more persuasive rationale than in this short scenario I would agree to a no adrenaline study

D.3 What are your views about the proposed “opt out” process?

Best that can be done in the circumstance. A robust external review/HDEC to protect patients interests is more important.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

No. Potential benefits are low. Possible harms are high. Should not be done without direct consent. If subject cannot consent then don't do

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

They are not the one who may be harmed

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes. They are often the people who will most benefit from improvements in care. If we cant research there can be no improved care.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

There has to be potential benefit. Potential benefits must be larger than potential harms. Harms should not be excessive

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Level standards. If you are in the health and disability field then same rules should apply.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- (•) No
- ( ) Unsure

2.2 Please give reasons for your answer

Dissent to part of the process does not mean the whole process should be discarded. I am an anaesthetist. By analogy, a patient who cannot consent for a general anaesthetic for a life saving procedure may dissent at IV cannulation or mask induction. Do we discard the whole process? No. Every precaution should be taken to ameliorate distress or accommodate dissent, but respect dissent in all cases? No

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Potentially new lifesaving therapies can be tested when consent cannot be obtained. Dabigatran reversal is now an accepted therapy because of that trial and could not be introduced without research with delayed consent.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ( ) Yes

- ○ No
- ◉ Unsure

4.2 Please make any further comments you have about question 4.1.

Unsure without an example

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

Alzheimers drugs may be tested in dementia in the future. Early trials will likely have no/little chance of improving care in the subject but could be a step to improving care in the future. If potential harms are low then yes. If not low, then no

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ◉ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	Reducing disability
2	Prolonging life
3	Reducing pain
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

A rule has to have teeth. Having HDEC as an option does not provide sufficient protection

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

Is there a community greater good?
Are the associated risks low?

7.3 Please state the reasons you formed this view.

Applying the previous rule will stop improvement in care in a population of great need.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- (•) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Assent is useful

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ◉ No
- ○ Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where this person is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA
2 Family
3 Researche
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

A new mechanism needs to be in place in NZ to allow research to improve care in patients who cannot consent. Appropriate ethical oversight is appropriate and desirable. The current legal impediment should be removed

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 20 March 2017 at 12:23pm | Completed on 20 March 2017 at 12:34pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ○ No
- ○ Unsure

A.2 Please give the reasons you formed this view.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- Yes
- No
- Unsure

B.2 Please give the reasons you formed this view.

B.3 What are your views about "delayed consent"?

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- Yes
- No
- Unsure

C.2 Please give the reasons you formed this view.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- Yes
- No
- Unsure

D.2 Please give the reasons you formed this view.

D.3 What are your views about the proposed “opt out” process?

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- Yes
- No
- Unsure

E.2 Please give the reasons you formed this view.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- Yes
- No
- Unsure

E.4 Please give the reasons you formed this view.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes, but with appropriate safeguards:
In clinical practice, the Intensive Care Physician will have the patients best interests of the patient as the only motivator, are therefore are in a strong position to make surrogate decisions about the patients care when they are not in a position to do so . The undertaking of a clinical trial acknowledges that clinicians don't always know which therapies are in the patient's best interests, and therefore to resolve this conflict, explaining this to a third party in each circumstance and obtaining their agreement that this is something the patient would agree to, introduces an appropriate safeguard.
Denying patients the opportunity to participate in properly conducted research would potentially deny them the opportunity to benefit either directly from a beneficial therapy, or therapies found in previous patients to be beneficial (and therefore become a 'standard of care'), and benefit from an improvement in the quality of service/protocol delivery that comes from an ICU being involved in well conducted clinical research. In short, if research in patients unable to give consent is not allowed, all research in the sickest patients (cardiac arrest, shock, severe sepsis) would stop, as would improvements in their care.
The Declaration of Helsinki8 and its revisions, to which New Zealand is a signatory, sets out provisions for medical research in patients unable to consent, where research is of potential diagnostic or therapeutic value for the individual participant. It also contains additional recommendations for when the patient is unable to consent, as well as provision for situations where research may require no patient consent9.
Recommendations include an independent committee to consider whether to approve the research. The regional ethics committees, acting as the independent review boards, have generally adopted a conservative but facilitative approach, consistent with the Declaration of Helsinki and the revisions9.
This ethos has been incorporated into legislation in Australia, England/Wales and Scotland, making clear provision for research on such patients, as outlined in the consultation document.

We support a change in NZ law in line with these jurisdictions, and appropriate safeguards, to allow patients with critical illness the right to be included and to ultimately benefit from advances in the knowledge of 'best practice' as applied to Intensive Care Medicine.

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1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- ( ) No
- (•) Unsure

2.2 Please give reasons for your answer

This is a very difficult question to answer. On one hand, when a loss of mental faculty creates uncertainty regarding a patient's capacity to be both informed and autonomous, ethical practice obliges medical practitioners to provide as much information and self-determination as is possible to the patient. The right to be involved in the decision making process, even with a diminished competence is protected by the Code (Right 7 (3)). At the same time the other three principles of beneficence, non-maleficence and social justice must be protected.
However, ICU patients who lack capacity are unable to comprehend the context or intention of the therapies which are being undertaken with the intention of preserving life and health. Patients would only find themselves on an ICU if they have become critically unwell (either through illness, trauma, or following major emergency or elective surgery). These processes all have the capacity to generate pain and fear. Most ICU therapies also have the capacity to induce discomfort, fear and anxiety during a consumer's journey in ICU (e.g. monitoring, pharmacological restraint, vascular access, diagnostic tests, basic nursing cares, mobilisation, weaning from ventilation, emergence from coma, removal of monitoring devices), and the careful steps we take to minimise their distress would add to the level of incapacity. Furthermore, many of our studies of two or more interventions as part of 'standard care' would be impossible for a patient to identify. It would therefore be very difficult to

differentiate the transient expression of fear and discomfort in the context of the above as a specific unwillingness to participate in research.
In practice, involving those who know the patient best (the family) in a conversation about whether they feel the patient would consent to being part of a trial may be the best way of incorporating an appropriate safeguard. Notwithstanding, Intensive Care Physicians are after all the guardians of very vulnerabe patients, whose best interests must remain the priority.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Yes; the reality is that this the current mechanism of conducting research in ICU's in NZ currently. If a consumer has been entered into a study based on the best-interests rule, and subsequently regains capacity ('recovers'), then the principle of informed consent means that delayed consent is a natural consequence of this process, and should be recognised by law. This remains preferable to the assumption that 'best interests' can override a patients subsequent withdrawl of presumed consent. An appropriate process of delayed consent with safeguards is outlined in Section 4.4.13 and 4.4.14 of the Australian National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research, updated in 2015

Reference
Australian Government : National Health and Medical Research Council- National Statement on Ethical Conduct in Hujan Research 2007 (Updated May 2015):
https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes
- ( ) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

Yes, although as outlined above, therapies of use in the critically ill should be proven to work on the critically ill.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**

- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- (•) Yes
- ( ) No
- ( ) Unsure

5.2 Please give reasons for your answer.

The key-word here is 'may'. Yes, presuming the research has the potential to benefit the patient. Again, this is a very difficult question: There are several potential benefits to the individual participant: In his analysis on this area, Gillet noted that "patients are better served in units where research is actively taking place for several reasons: i) they do not fall prey to therapeutic prejudices without clear evidential support, ii) they get a chance of accessing new and potentially beneficial treatments, iii) a climate of careful monitoring of patients and their clinical progress is necessary for good clinical research and affects the care of all patients and iv) even those not in the treatment arm of a trial of a new intervention must receive best current standard care (according to international evidence-based treatment guidelines)".
The NHMRC Document states: "Research involving people who are highly dependent on medical care may be approved where: -it is likely that the research will lead to increased understanding about, or improvements in, the care of this population….People highly dependent on medical care may be exposed to severe threats to their lives, so that recruiting them into research might seem unfair. However, those people are entitled to participate in research and, when the conditions of paragraph 4.4.1 are met, their involvement is not unfair"13.
UK law contains the appropriate safeguards in this regard: Research can take place on people who lack the capacity to consent only if that research:
"Either
¥ has the potential to benefit the participant without creating a disproportionate risk
or

¥ is intended to provide knowledge of the causes or treatment of, or care of, people a affected by a similar condition. If so, researchers must have good reason to believe that any risks to individual participants are negligible, will not significantly impact their freedom or privacy, and will not be unduly invasive or restrictive.
"

The law could be amended to allow research to be conducted more in accordance with UK law: such that the wider public benefit can be a consideration only If there's 'minimal' harm/burden to the patient.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- (•) Yes
- ( ) No
- ( ) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	Potential to benefit the p
2	Minimal burden or risk (
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (●) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Yes: The College fully supports the notion that there should be independent checks and balances, for example as outlined by Rincon et al: " [with] the imposition of safeguards such as consultation with the community in which the study were to take place, oversight in patient screening and recruitment process by institutional review boards, special study designs, retrospective and prospective consent processes, and independent safety monitoring" 6.
The College supports a process in line with Section 4.4 of the Australian NHMRC Statement.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (●) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

Do you think the current best interests test, which requires that the consumer would be better-off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

This question has several qualifiers, and is therefore not a straightforward yes or no. Intensive Care Physicians have a duty to always act in the best interests of the patient, however the best interests test is inferior to a model of delayed consent after obtaining family assent, due to the fact (as outlined in the HDC document) "that it is difficult to predict accurately to a participant the risks and benefits of the research. The benefits could include a potential improvement in a medical condition, the prevention of further deterioration, and/or the prolongation of life. Best interests may also encompass non-medical factors such as emotional and other benefits."

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- ( ) No

Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

Yes

No

Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

In all cases where an EPOA or welfare Guardian is available?

Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)

Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?

Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

Consulted by decision-maker

Power to veto consumer's participation in the research

Provide or withhold consent on behalf of the consumer

Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?

- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1
2
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Executive Summary
The College of Intensive Care Medicine of Australia and New Zealand (The College) is the body responsible for the training of Intensive Care Medicine (ICM) Specialists and the accreditation of Intensive Care Units (ICU's) for training in New Zealand and Australia. The College is committed to achieving the best health outcome for critically ill patients, through training high quality specialists, increasing specialty knowledge and improving standards of care.
The College fully supports the notion that increasing knowledge to improve patient care is best achieved by following the principles of Evidence Based Medicine (EBM). EBM is the conscientious, explicit, judicious and reasonable use of modern, best evidence in making decisions about the care of individual patients. EBM integrates clinical experience and patient values with the best available research information. In order to implement EMB to achieve the best outcome in our patients, Intensive

Care clinicians will be expected: a) to use evidence summaries in clinical practice; b) to help develop and update evidence-based guidelines in their area of expertise; and c) to enrol patients in studies of treatment, diagnosis and prognosis on which medical practice is based2.
An integral part of improving standards of care involves using best evidence to inform which interventions maximise the chances of achieving good patient outcomes, and allow those interventions which are either non-beneficial or harmful to be discarded. There are numerous examples of therapies which on initial 'experience' or low-level evidence- appeared to have been beneficial to patients, only to have been shown to be potentially harmful in the context of a well-designed multi-centre Randomised Controlled Trial (RCT), for example the CHEST, NICE-SUGAR and the SAFE-TBI studies,,.
New Zealand and Australia has produced some of the largest and well conducted ICM research, driven by the Australia and New Zealand Intensive Care Society Clinical Trials Group (ANZICS-CTG). and we believe this is reflected in our world-leading outcomes from diseases such as sepsis, and a reduction in the relative risk of death from sepsis of 47% between 2000 and 2012.
However, the College acknowledges that research on patients who lack capacity is a very sensitive issue, and that the role of Intensive Care Physicians is firstly (and foremostly) as an advocate for and carer of the patient.
The four key ethical biomedical principles; Autonomy, Beneficence, Non-Maleficence and Justice are potentially under tension in the context of research. Failure to respect autonomy in the pursuit of the 'greatest good for the greatest number' has been at the heart of some of the worst historical atrocities in the name of advancing knowledge through research. The Nuremberg Code of 1947 and the Declaration of Helsinki in 1964 cemented autonomy as the most important principle in this regard.

Please state your name

(on behalf of the board)

Organisation (if applicable)

The College of Intensive Care Medicine of Australia and New Zealand

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 20 March 2017 at 9:36pm | Completed on 20 March 2017 at 10:18pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

This treatment is the standard care and the study is measuring what is occuring anyway. While it may not benefit myself on this episode it might should I survive and get sepsis again! The tests will be able to be gathered through the normal routes of testing and are unlikely to harm me.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

The risk of excluding those unable to give consent prior means there are likely to be confounders of not treating those with more severe disease. This would mean any result is only valid in those able to give consent. This then is likely to disadvantage a already impoverished group. Those of lower educational level or lower socioeconomic groups present later and more severely. Excluding these groups disadvantages them as they are not forming part of the result. Without true randomisation both products are then subject only to the manufacturers claims not the patients best interests to choose between them.

B.3 What are your views about "delayed consent"?

It is a fair compromise when a consumer is unable to initially consent so they are able to withdraw from further follow up should they not want to. Any trial should allow the withdrawal of consent by the patient, until the conclusion of data collection.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

The alternative to this is that a home is set up with no evidence and advertises this approach as beneficial with no evidence except opinion. It may be that diminished contact leads to better outcomes but without a randomised trial the only decider is advertising and market forces not evidence.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (●) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

I would love this study to happen! Just because something is the standard of care doesn't make it the best care. Without comparing treatments we can't improve care. I would rather be alive walking out the hospital or dead than dependant. If Adrenaline is more likely to lead to the latter I would not want to be resusitated using it. The method of removing consent is novel and unlikely to work, or at least remove a higher socioeconomic group who follow news. This disadvantages them .

D.3 What are your views about the proposed “opt out” process?

I think it is a poor idea that doesn't allow for true informed consent, for example poor vaccination rates. Often opinion pieces and non evidence based arguements are made due to influencers with bias.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ○ No
- ◉ Unsure

E.2 Please give the reasons you formed this view.

I would want the risk of suicide quantified and the improvement in cognition well defined. And a stop early cut off. THere is a definate risk to the consumer and the increase in cognition may not lead to any meaningful imoprovement that leads to decreased dependance.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ◉ Yes
- ○ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

If the above points are clear then friends and whanau may be able to help the consumer decide if they should participate.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes, these patients are critically unwell and often require treatment decisions quickly. Studying in this setting is already difficult and adding getting consent from reletives can lead to detriment in care.
This group are often disadvantaged already and removing the ability to improve care in these this group of society further disadvantages them from being able to recover to a prior quality of life.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

There should be no other group that could be studied and give consent. That there is equipose between therapies or little/no evidence in this group. Results should be published even if negative.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- ( ) No
- (•) Unsure

2.2 Please give reasons for your answer

A facial grimace is difficult to interpret if there is associated pain or possible cognitive clouding. It may be distress at being unable to comunivcate rather than declining consent. A clear expression of dissent that is unequivocal should be respected. However this could be difficult to adequately define.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

The option for comparison of therapies could be passed and missed.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ◉ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
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Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

It gives a safeguard that the research can't be carried out in another way. Hoever the position should be to encourage this research safely rather than placing a barrier to it.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

That there is equipose or non equivilance between therapies or tests.

7.3 Please state the reasons you formed this view.

Often theraopies have minimal evidence but a wieght of opinion behind them . the only way to improve is to test/trial.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ◉ No
- ○ Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where family or whanau is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☑ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ◉ No
- ○ Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where a provider not involved in the research is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ◉ No
- ○ Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where this person is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 researcher
2 Consumers responsibl
3 EPOA
4 Whanau
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 23 March 2017 at 4:14pm | Completed on 23 March 2017 at 4:56pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

The results of this study would lead to more accurate dosing of antibiotics for future patients in ICU.

With such a study, once the participant has recovered, they would be offered the chance to have their data removed from the study should they so wish.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

If there is clinical equipose as to the best technique, then it is important that this is tested accurately.
The randomisation process allowing for the different neurological conditions would need to be carefully looked at.
Assuming appropriate study design, this would be suitable.

B.3 What are your views about "delayed consent"?

For a number of clinical scenarios, it is important to gain the best possible clinical information for management. In the ICU setting, this is critical. However, consent is clearly difficult, but assuming it has passed the rigors of a HDEC review, then delayed consent is very valid.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

Again, with the appropriate safe guards of both scientific valdity (by independent peer review) and HDEC with respect to the ethical issues related to the study and how it was managed. This would be appropriate. The outcome is to improve dementia care. Progress can not be made with out proper scientific inquiry.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

I have major concerns over the scientific validity of the proposed study. There are alternative agents to compare to adrenaline, if there is to be a comparison. This study which would be placebo controlled would have significant issues. Likewise the actual number of events needed to show any sort of difference is likely to be very high and subject to considerable confounding.

D.3 What are your views about the proposed “opt out” process?

Opt out is valid for some specific purposes, but for a study design such as this it is totally impractical. The numbers required compared to an actual event would be vast.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ○ No
- ◉ Unsure

E.2 Please give the reasons you formed this view.

There are two different questions here.
1. should individuals with Downs syndrome be invited to take part in any clinical study?
2. Should this particular study be run in Downs syndrome individuals unable to give consent?
with respect to 1, yes they should be able to participate in appropriately devised studies where their safety is protected and has been reviewed as ethically sound. Consent by a family / whanau member is appropriate - accepted practice for studies in children.
Have issues with the study design as it is given so for point 2 , requires much greater clarity of protocol etc.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ◉ Yes
- ○ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

Would qualify this as it depends on the study design and intervention. The same applies for studies with child participation.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes. There are many situations where greater evidence for the best standard of clinical practice needs to be examined. Particularly in the ICU situation. Any 'new' or novel intervention needs to be proven to be of benefit. Likewise, studies of drug clearances or drug handling that can be greatly changed by the clinical situation of an acutely unwell patient, means that accurate data needs to be obtained. With current limited health resources which prevents immediate point of care testing (unfeasible in many cases), this precludes immediate feedback to the actual individual's management at that time point. Never the less their participant, may impact upon their care as soon as results available, but will definitely help future individuals in a similar situation. The majority of individuals will have an alturistic component in their nature and to deny this is not acceptable.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

Again, the safe guards that are in place via the Ethics committees means that the individual is protected to the best of intent. It is the law that changed the condition, previously ethics committees accepted such research. Which has made major differences to clinical management. This is currently at risk and putting clinical management with evidence based mediciine at increased risk.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

The majority of academic research does actually come under the h&D issues and is reviewed by university ethics committees under the same guidelines as HDEC

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Yes this is vital for the reasons given in some of the above cases.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes
- ( ) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- (•) Yes
- ( ) No
- ( ) Unsure

5.2 Please give reasons for your answer.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- (•) Yes
- ( ) No
- ( ) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	improvement in clinical
2	Providing evidence bae
3	
4	
5	

Any others?

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- (•) Yes
- ( ) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes

- (●) No
- ( ) Unsure

Additional comment.

The current HDEC are well versed and able to make appropriate decisisons.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (●) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)

- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

The first option is reasonable, but not always practical. there needs to be flexibility related to the particular study design

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Family
2 EPOA
3 Provider not involved
4 Researcher
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 24 March 2017 at 1:18pm | Completed on 24 March 2017 at 2:30pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

Given this is a purely observational study and doesn't affect the treatment that I as a patient would receive, I would be happy to be included as a participant in the study. I think that it is also a big factor that the topic being researched can only be studied with the inclusion of non-consentable participants (it is safe to assume that all haemodyalisis patients in ICU requiring antibiotics will almost all be non-concenting). Since, the topic being studied is of great importance and benefit to future patients, for these reasons I would be fine with being included in the study.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ○ No
- ◉ Unsure

B.2 Please give the reasons you formed this view.

Given that the two products being tested are both approved, I wouldn't have a problem taking part in this study. However, I don't think in this case there is a necessity to include non-consenting patients. There are enough patients that are able to consent for research under elective admissions, therefore I don't think it is appropriate to include patients that are not able to consent for themselves. In addition, the topic being studied does not specifically help present or future patients with severe neurological deficit requiring neurosurgery in a significant way. I think that non-consenting patients should be included only if it is necessary to complete the research.

B.3 What are your views about "delayed consent"?

I agree with the concept of "delayed consent". Although the intervention cannot be undone, it gives the option for patients to withdraw all information as part of being put in the study, as well as destruction of any blood or tissue samples collected as part of research, if they were unhappy with their inclusion in the study.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ◉ Yes

- ○ No
- ○ Unsure

C.2 Please give the reasons you formed this view.

Given that the study has the potential to be of benefit to the participant, I would be happy to participate. The study should consent patients that are able to consent for themselves, but the inclusion of severely demented subjects is also necessary because it is also the group that would benefit the most from the results of the study. The study information derived from the severely demented group would also be incredibly valuable information towards the effectiveness of each type of care.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ◉ Yes
- ○ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

Given that it is standard of care to give adrenaline and there is a body of knowledge from prior research suggesting that adrenaline may be harmful, I would be fine with being included in the study. In addition, given the potentially very important information the results of the study would provide I would be happy to participate based on the fact that it is a very necessary study to be done.

D.3 What are your views about the proposed “opt out” process?

In theory it is a good concept, but I'm not convinced with how practical it is. Especially for the example, it would be impossible to ensure that the public campaign would reach everyone as it is difficult to determine who is at risk of suffering from a heart attack. A campaign with massive reach to ensure everyone got the message would also be incredibly expensive to run. It would be also difficult to determine who the target audience would be, because people without obvious risk-factors can also be possible participants.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- (●) Yes
- ( ) No
- ( ) Unsure

E.2 Please give the reasons you formed this view.

The study would provide the participant direct benefit for participating, so I would be happy to participate. Given that the study drug went through rigorous safety testing to get to this point, I would also think it is reasonably safe to take as well; so the risks are minor.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- (●) Yes
- ( ) No
- ( ) Unsure

E.4 Please give the reasons you formed this view.

I think that caregivers should definitely be consulted for participation. I also think that if a caregiver is responsible for making medical decisions for a person with cognitive deficit, they should also be allowed to make the decision for them to participate in research.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes, absolutely for studies where patients receive direct benefit. I also think studies that could result in an important body of knowledge towards to care of the unconsentable patients, should also be allowed to include them if the study design provides minimal risk towards the participant. Without such studies, it would result in a huge lack of knowledge that would significantly stunt improving care for these patients. I think that the "for the greater good" is a very important factor in allowing non-consenting patients into studies.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

The study should only include non-consenting patients if it is necessary i.e. when majority of patient group studied are unable to consent.
Study should be of minimal risk to the participant, if it doesn't provide direct benefit e.g. comparing 2 standards of care.
Intended study results should be worthwhile doing, and significantly contribute towards improvement of care of the non-consentable patients.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Academic research should also be within the jurisdiction of the commissioner. It is even more important because a lot of academic research groups are unaware if ICH-GCP. The patients included in academic research should be protected by the Commissioner, and to me, it is shocking that this is not the case at present.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Researchers should be sensitive to the possibility that a non-consentable patient does not want to participate. If the patient is noticeably distressed by the study related interventions, the patient should be withdrawn because it is causing a negative response. Having said this, it would be difficult to standardize what is considered an expression of dissent, especially because it would depend on the situation. (e.g. post-op, chronic pain, etc that would also cause a negative facial experssion)

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

I have worked on studies that used delayed consent so I'm not sure if it is actually not permitted by law. My experience from patients is positive, especially because the study was of direct benefit to them.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes
- ( ) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

If a study has a mixture of non-consentable or consentable patients, the researchers should attempt to complete the study with only including the consenting patients. If the study is unable to do so, then the issue should be revisited to include non-consenting patients. I think this should be a requirement by law.

If at the initial ethics meeting, the researchers are able to prove that the study cannot be done without nonconsenting patients, then they should be allowed to include them.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- (•) Yes
- ( ) No
- ( ) Unsure

5.2 Please give reasons for your answer.

I personally think that as long as there is minimal risk to the participant, they should be included in the study, if the study will improve care in that group of patients.

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- (•) Yes
- ( ) No
- ( ) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1 [ ]
2 [ ]
3 [ ]
4 [ ]

5

Any others?

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

This is an absolute must in my opinion. There needs to be a committee consultation to ensure that the most vulnerable group are protected.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

I think the threshold is too high currently, and it doesn't allow for standard of care comparisons, which would be beneficial for society but not directly to the participant.

7.3 Please state the reasons you formed this view.

I think that when assessing a study, it needs to consider the balance between benefit/risk to the participant and benefit to society and future patients. The progression of improving care is also a very important factor to consider, which I do no believe is adequately weighed in the current approval process.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (●) Yes
- ( ) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (●) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where an EPOA or welfare Guardian is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

It would be unfair to ask EPOAs to consent at distressing times, but if they are in a position where they are able to make an informed decision for their loved one, they should be allowed to decide.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

If an EPOA was appointed by the participant to make medical (and possibly other) decisions on their behalf, they should also be allowed to make decisions for participation in research. The participant provided their trust to this person, and I think the

EPOA would have a better understanding than an independent medical doctor whether or not that person would want to participate in research.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's

life or preventing serious damage to the consumer's health.)

- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA
2 Provider not involved
3 Family/Whanau
4 Researcher
5 Other

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

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Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

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Started on 28 March 2017 at 8:49am | Completed on 28 March 2017 at 9:33am

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

This non-therapeutic observational study addresses an important research question which cannot be answered except by using this group of patients. Although it does not directly benefit the participants there is minimal risk.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Further justification is needed for using participants who are unable to consent. Is this just a question of gaining statistically relevant numbers or is there some other reason for their inclusion in this comparative effectiveness study.

B.3 What are your views about "delayed consent"?

When the patients regain capacity it seems reasonable in this case to allow them to have their data removed from the study.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

All participants in this study are receiving, at least, standard care. The committee would want to be assured that the researchers have adequate protocols for removing participants from the study if they do become more agitated or distressed.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ○ No
- ◉ Unsure

D.2 Please give the reasons you formed this view.

The committee would want to see peer reviewed evidence that supports the claim that the current treatment has resulted in poor outcomes.

D.3 What are your views about the proposed “opt out” process?

The opt-out process raises questions as to its likely efficacy. It seems that a massive public awareness campaign would be needed in order to reach the target population. Would every over 50 year old be reached and educated about the trial?

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

The risks in this trial outweigh any potential benefits, especially as the drug would be unavailable,at the conclusion of the trial. The safety profile of the drug raises concern.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Well planned and regulated research has the potential to improve treatment protocols and those improvements should not be restricted to those who can consent to participate. However this non consenting group of participants should only be included if this is the only way to answer the research question, such as in cases ....

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

Depends on the type of study - non therapeutic research should carry no more than minimal risk and discomfort. All research should be approved by an independent research ethics committee with appropriate expertise. If consent cannot be obtained then assent should be sought and dissent should always be respected.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- ( ) No
- (•) Unsure

3.2 Please give reasons for your answer.

In some situations retrospective consent is a nonsense - when drugs have already been administered for example. In other cases however it can be useful such as consent to continue as a research participant if the research is ongoing or consent to have ones data included in the study. (such as in case ....)

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Not sure if this needs to be a legal requirement but researchers should be required to demonstrate to the ethics committee that this requirement has been met. This can be done through good peer review.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

See COIMS guideline 16

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

It provides an independent

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- ( ) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- ( ) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (●) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (●) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
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Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where this person is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
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Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
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- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
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- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1
2
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

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Thank you for your contribution to this consultation.

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Started on 29 March 2017 at 8:43am | Completed on 29 March 2017 at 9:22am

Health and disability research involving adult participants who are unable to provide informed consent

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In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

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The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

The research does involve additional risk. Usual care is being provided and the results could improve care.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Both arms of the trial are usual care so risk is minimal

B.3 What are your views about "delayed consent"?

It is respectful. People can decide when they become competent.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

I could benefit and there is no other way to research this.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

I might not have not heard about the study and not opted out and would therefore be given the study medication (adrenaline or placebo). I would not want to be in a study where there was a chance that I would not be given what is currently considered best practice.

D.3 What are your views about the proposed “opt out” process?

I think it is ethically sound and I would want this option. However in the case study described above it would be difficult to know that everyone who wants to opt out has had the opportunity to do so i.e have heard about the study and opting out and have had enough information and time to opt out and how to do this. There will also be people who want to opt but haven't got around to doing it or do not feel comfortable accessing the process to do so.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ○ No
- ◉ Unsure

E.2 Please give the reasons you formed this view.

I feel uneasy about the level of risk involved for the participant. There would need to the protection that consulting with family/whanau/caregivers would provide.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ◉ Yes
- ○ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

I think this is extremely important because they are the people who know if this would be in the best interests of the patient.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes because improvements in healthcare can be gained.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

People must be able to provide delayed consent where possible or their family members to make the decision on their behalf. If there is no or minimal risk to the individual and/or potential or definite benefits they should be enrolled with the proviso of delayed consent being obtained.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

People with health and disability issues are vulnerable and there needs to be safe guards in place no matter who is doing the research.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Everyone has the right to choose for themselves what they want to do and however this is expressed must be respected. I realise that facial expressions etc can be open to interpretation so there would need to safe guards in place such 2 people independently assessing what the person is communicating.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- ( ) No
- (•) Unsure

3.2 Please give reasons for your answer.

The research would need to be low risk i.e like observational studies otherwise the researchers should try and ascertain the persons wishes form family etc

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

This seems the safest way of doing things

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

How else can this information be obtained.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ◉ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	No harm to the participa
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- (•) Yes
- ( ) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Family/whanau
2 EPOA
3 Provider not involved in
4
5 reseracher

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 30 March 2017 at 2:43pm | Completed on 30 March 2017 at 3:40pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

Yes, I would be willing to participate provide adequate safeguards were in place. Such safeguards include that the research has approval from an ethics committee and from the health organisation (such as a district health board) in which it was undertaken, and is undertaken in accordance with the "General Principles" of the Declaration of Helsinki and its revisions. Because the study described in Case Study A is observational research rather than interventional research it is by definition very difficult for the research to be proven to have a "likelihood of benefit"; however, this type of research as presented in the case study could not be conducted in another patient group (i.e. patients capable of giving consent), it does seek to address an important clinical question which promotes the health of the group represented by the potential participant and the observational procedures described in the case study which are additional to usual care (i.e. extra blood and urine tests) do not present more than minimal risk or burden to the potential study participant.
In my view it is unethical not to be able to undertake observational clinical research across the wide range of conditions in which patients may not be able to consent (emergency medicine, intensive care medicine, paediatrics, dementia) for the reason it would not be possible to gain the knowledge of physiology, biochemistry, pathology etc that underpins the advancement of diagnosis, prevention and treatment of diseases and ill-health in such patient populations. This would mean that it would never be possible to determine the optimal management regimens in such conditions, improve standards of care and establish the evidence base of many medical practices for which the efficacy/safety profile has not been determined.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

I would be willing to participate provided adequate safeguards (for example the safeguards outlined in A2 of ethics approval etc) were in place. The research scenario described compares interventions which are in current usage and for which the comparative efficacy/risk profile has not been established. In addition, please note that the Declaration of Helsinki clearly states that "Even the best proven interventions must be evaluated continually…" and sets out conditions and procedures for medical and surgical research in patients who are unable to consent and I would consider this research to be consistent with these.

B.3 What are your views about "delayed consent"?

In terms of delayed consent this should represent a capability to opt out rather than the requirement to opt in.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

I would be comfortable to participate in this research as in addition to the safeguards outlined in my responses to the previous scenarios there is the additional provision for my next-of-kin to provide informed consent on my behalf as a further safeguard to protect my interests. As stated above, it would be worthy to note that if it was not possible to undertake research in persons with dementia who are unable to consent, it would not be possible to establish any evidence-based medical practice in this common disorder, which would be in my view unethical. It would also mean that future persons with dementia who are unable to consent would be unable to benefit from such evidence-based practice.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (•) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

The value of participation in a research study of the type described in case study D is supported by the example of the change in medical practice which has occurred as a result of research which has shown that previous CPR practice led to worse outcomes than the novel approach which focused on cardiac compression rather than pulmonary resuscitation. If this research had not been undertaken because such patients do not have the capacity to give consent in the situation of a cardiac arrest, the continuation of current practice would have led to an acceptable, avoidable risk of mortality and disability. Another good example is the regimen of cooling patients following a cardiac arrest which improves outcomes. If this research had not been undertaken in patients who clearly did not have the capacity to give informed consent, the evidence base for this novel practice would not have been established and patients would not have been given the opportunity to receive this treatment. There are additional current practices in relation to cardiac arrest, e.g. the administration of high flow oxygen therapy, which do not have a satisfactory evidence base yet are commonly used in clinical practice.

D.3 What are your views about the proposed “opt out” process?

I think the proposed process for "Opting out" including the use of a public information campaign to raise awareness of the "NO STUDY" bracelet is appropriate.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ○ No
- ◉ Unsure

E.2 Please give the reasons you formed this view.

As in the case relating to dementia, in principle I think that persons with Down's Syndrome who are unable to consent should still have the opportunity to participate in clinical research. In any such research in this patient group there should be the additional safeguard that the next-of-kin or primary family/whanau/caregiver gives informed consent on behalf of the person with Down's syndrome. However, I have answered this question "Unsure" because there are some elements of the particular research scenario as described which concern me. I would require further clarifications of the research proposal detail, scientific assessment and evidence that possible risk did not strongly outweigh possible benefit. I would also want to see significant revisions to the outlined process for consultation with family/caregivers, and for family/caregivers to have the opportunity to provide consent, and the participant to provide assent if possible.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

No I do not think that this proposed consultation (which mirrors an opt out process) is appropriate, as the primary caregiver who has responsibility for the wellbeing of the person with Down's syndrome must have the capacity to provide informed consent for such research. Enrolment into this study is taking place in the context of a permanent disability – there is no justification for using an "opt out" style process for enrolment. Only those potential participants whose primary caregivers are willing to affirm their decision that their relative should participate in the study by completing a written consent form should be enrolled.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes, research would definitely be allowed to proceed with adult participants who are unable to provide informed consent. The reason for this is that there are many clinical situations in which patients are unable to provide informed consent, due to the nature of their condition, in which there is an unsatisfactory evidence base to guide management. This means that patients are currently receiving management which may cause avoidable harm and/or not receive management which would improve outcomes because of the lack of sufficient research undertaken in the past, or because new therapeutic approaches had not yet been tested. If the patient who is unable to provide informed consent, or subsequent patients to follow, are to receive optimal management which both improves clinical outcomes and reduces risk of harm, then it is mandatory that such research is undertaken with appropriate safeguards to protect their interests. If it was mandated that adult participants who are unable to provide informed consent should not participate in research, then we really are returning to the dark ages of medicine where medical management is undertaken without a satisfactory evidence base for its efficacy and safety.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

In my view no specific restriction should apply but rather adequate safeguards should be put in place. These would include approval from an accredited ethics committee (HDEC), the health organisation in which the research is undertaken, and in the case of medications or devices not approved in New Zealand, SCOTT approval. The research would also need to be undertaken in accordance with the Declaration of Helsinki and its revisions, to which New Zealand is a signatory.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (●) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Clearly the same rules should apply to all health and disability-related research as the key issue here is that the rules should apply in the interests of the patient, not be determined by the research team.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- (●) No
- ( ) Unsure

2.2 Please give reasons for your answer

This would depend on the situation in which the person may express some dissent or refusal. Certainly there would be situations in which this would be important, however there are some situations such as in delirium associated with an acute severe illness in which such expressions may relate to the delirium rather than the informed wish of the patient. Due to such differences in different situations in my view the law should not expressly have this provision.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

I was surprised by the interpretation that delayed consent is not permitted under New Zealand law. My understanding is that it is legal for critically ill patients who may not be able to provide informed consent to be enrolled in a study that is in their best interests and if they subsequently regain capacity, it would be ethical and required to obtain their informed consent for their ongoing participation in the research which by its very nature at that stage would be delayed. In view of the apparent uncertainty regarding the interpretation of the current legal situation, I think it would be a high priority for this to be clarified with the express provision of delayed consent.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ( ) Yes
- (•) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

While I think that this is a good principle and should be the preferred approach in normal circumstances, there are some circumstances in which research of a similar nature cannot be adequately carried out on competent persons. An example here would be the treatment of life-threatening influenza treated in Intensive Care during a pandemic influenza. By the time research of a similar nature was undertaken in competent less sick persons the pandemic may well have finished with an unnecessary loss of life due to the inability to undertake research in the most critically ill patients during the pandemic.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- (•) Yes
- ( ) No
- ( ) Unsure

5.2 Please give reasons for your answer.

Whilst as a general rule participation in research improves outcomes for the participants, the primary goal of clinical research is to improve management of future people with the same condition. To require research; particularly observational research and research comparing different treatments or a treatment and a placebo, to benefit every individual participant in the research is in many instances going to be an impossibility. The purpose of research is to answer questions such as to find out the risk/benefit profile of differing randomised treatments and if this knowledge was already obtained, the research would not be necessary. This presents an ethical challenge– i.e. for Researchers to design scientifically meaningful studies that are not unethical. Therefore because research in most instances is being undertaken for the benefit of future people with the condition being investigated there must be rigorous ethical review and scientific assessment processes in place to determine the validity of proposed research and to determine and assess the risk benefit ratio to participants, thereby ensuring that the interests of the participants in the research are protected. These assessments are particularly important in the case of participants who are unable to consent to ensure that the proposed research does not expose them to unacceptable levels of risk or place an undue burden on them.

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ◉ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- ◉ Yes
- ○ No
- ○ Unsure

6.2 Please give reasons for your answer.

Ethics committee approval should be mandatory in all cases where research involves adult patients who are unable to provide informed consent.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

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7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ○ Yes
- ○ No
- ◉ Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

This is a difficult issue as doctors always have a duty to act in the best interests of the patient. However, protection of the rights of patients who are unable to give consent needs to be undertaken at multiple levels, including approval by an ethics committee, the organisation in which the research is being undertaken, and SCOTT approval with novel medications or devices, with the subsequent opportunity for the patient to provide delayed consent, as well as discussion with the next-of-kin/primary caregiver.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? *Please select all that should apply, or provide comment below if you prefer.*

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?

☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

The EPOA or welfare guardian should be consulted if available in a timely manner, and does not lead to a delay in treatment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

☑ Consulted by decision-maker

☐ Power to veto consumer's participation in the research

☑ Provide or withhold consent on behalf of the consumer

☐ Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

◉ Yes

○ No

○ Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

☑ In all cases where family or whanau is available?

☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)

☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?

☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

It does depend to some extent on how close the family/whanau is to the patient.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Seldom.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

Please specify who.

There may be some situations where other persons may be worthy of consultation.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where this person is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

There may be some situations where other persons may be worthy of consultation.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

There may be some situations where other persons may be worthy of consultation.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**

- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Researcher if they are t
2 EPOA
3 Family/whanau
4 Provider
5

8.5 Please provide any other comments you wish to make about the decision-makers.

In the case of research in the settings of emergency and intensive care medicine, the ultimate responsibility would need to lie with the researcher who would be the health professional providing the management for the patient.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

onsultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 31 March 2017 at 2:34pm | Completed on 31 March 2017 at 7:01pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

There is potential benefit to others and no risk to the subject. The benefit to others may also include benefit to the subject if they are in the same position later.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

There is no evidence to say that one treatment is better than the other. The study might provide that evidence, and the alternative is that the subject is randomly given one treatment or the other with no benefit obtained.

B.3 What are your views about "delayed consent"?

Delayed consent is appropriate if there is no additional risk from the study. It is particularly appropriate if asking for consent prior to the experiment could alter the subjects response; as could occur in many psychological and behavioural experiments.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

As a participant, I would not have a concern.

As a scientist, if people did become distressed and were unable to continue in the experiment, then a last-observation-carried-forward approach might lead to a progressive dilution of the results and the study becoming inconclusive.

On balance, if people were able to be withdrawn if the interventions did become too much, I would be in favour of it.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

Scientifically as well as ethically this seems a poor design. A better design might be to do a less rigorous but simpler study, perhaps ceasing using adrenaline and measuring outcomes before and after this time. For such a critical treatment, having the widest possible set of advice and consultation seems very important.

D.3 What are your views about the proposed “opt out” process?

This is about the stupidest thing I have ever heard.

Consider a group of psychology students, who may be suddenly 'surprised' with a Milgram-esque experiment - but who may opt out by wearing a bracelet etc. this seems appropriate.

For the general public who are ill-educated and unmotivated it seems inappropriate.

An opt-in system (like organ donation cards), seems more appropriate, although unlikely to result in a good experiment.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

Risks seem to outweigh the benefits in a vulnerable population.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

The PPPR Act does not (I think), allow someone to consent to experiments for another or treatment that is not in a persons best interests. If the legislated means of substituted consent does not allow it, then an 'informal' system should not either.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

If the research is regarding therapies that would be used anyway, or there is no additional risk then yes.

Again, if there is a possible benefit to self or others and no risk, then research in patients who could provide delayed consent should be permitted.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

Even with no formal substituted consent in place, it would make sense to me to have a family member, patient advocate or committee consulted.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- ○ Yes
- ◉ No
- ○ Unsure

1.4 Please make any general comments you have about question 1.3.

The Commissioner and the Code are only enforced on people providing health and disability services. Other institutions have their own research and ethics frameworks.

Where it is clear that research is not part of the subject's health or disability treatment, the code should not apply.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ○ Yes
- ◉ No
- ○ Unsure

2.2 Please give reasons for your answer

The statement is illogical. If someone is capable of expressing dissent or refusal, then they are expressing a choice. The current consultation is about persons who are INcapable of making that choice.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ◉ Yes
- ○ No
- ○ Unsure

3.2 Please give reasons for your answer.

For risk-free or very low-risk research, yes. But only if the research is otherwise ethically and peer supported.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (●) Yes
- ( ) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- (●) Yes
- ( ) No
- ( ) Unsure

5.2 Please give reasons for your answer.

I think a similar standard to the decisions about treatment should apply. If the subject has said that they give prior approval to any research ("I will leave my body to science"), then all might be possible.

Otherwise research that would be likely to benefit them in the future (similar condition, similar other characteristics etc), then yes.

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- (●) Yes
- ( ) No
- ( ) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	similar condition
2	similar demographics
3	
4	
5	

Any others?

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

I thought all intentional research was already required to be approved. I would support researchers being required to openly flag if incompetent persons were being used.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

As in Question 5.1 - 5.3. I would support this being broadened form "best interests of the consumer" to either

"best interests of similar or related consumers"

or even

"best interests of consumers"

7.3 Please state the reasons you formed this view.

If the research is not going to produce benefits, then broadly it should not be done. If it is gong to produce benefit, if not for a particular consumer, at this particular time, then I support research that might have benefitted this consumer or would benefit a person in the similar position in the future.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ○ Yes
- ◉ No
- ○ Unsure

Additional comment.

I do not see any change is necessary to implement any changes suggested. I think that a change in the Code or even commentary and guidelines to the code would be sufficient.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ◉ Yes
- ○ No
- ○ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☑ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

If available, they should always be consulted.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☑ Consulted by decision-maker
- ☑ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

In keeping with informed consent principles, even if the decision-maker is not being required to make a choice, they still have a right to be informed.

I think this should also be an opt-out point. The EPOA / Guardian deciding yes will not on it's own be sufficient if the other tests are not met, but if the EPOA / Guardian decides no, then the research should not continue.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Always involved and have a right to information about research.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

The family will often hold the most relevant information about what a person's most likely choice would be.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

As part of the usual approval of research process.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Researcher should be able to demonstrate general peer support for the research.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

Please specify who.

Persons already involved in Ethics approval (other non-interested researchers, experts, lay-persons etc).

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Researcher
2 Guardian
3 Provider not involved
4 Whanau
5

8.5 Please provide any other comments you wish to make about the decision-makers.

The researcher may be the person to start the process rolling, but at the end they also can make the choice not to proceed.

Final comments

9. Please add any final comments or suggestions you wish to make.

I do not believe the Code or the Act need to directly address research. I think that treatments are already covered in the normal policies of the Code, while research is covered by the ethics committees created by the Act itself.

Please state your name

Organisation (if applicable)

Personal

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 5 April 2017 at 6:52am | Completed on 5 April 2017 at 7:42am

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ○ No
- ◉ Unsure

A.2 Please give the reasons you formed this view.

As the urine and blood tests are often part of routine clinical management and there are no other changes in clinical management this could be seen as not raising objections.However, it is still not informed consent that benefits the person

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ◉ No
- ○ Unsure

B.2 Please give the reasons you formed this view.

Is not informed consent and one group of patients is having potential benefit withheld without their knowledge

B.3 What are your views about "delayed consent"?

I cannot see any research circumstances where it would be justified

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ○ Yes
- ○ No
- ◉ Unsure

C.2 Please give the reasons you formed this view.

Initially should only be those able to consent. Perhaps a case for discussion with relatives/EPAs.
However, should be strictly monitored and intervention ceased immediately in individual cases if signs of distress etc

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

Way of selecting random sample is too random- could have a target group of potential participants e.g. "members" of Heart Foundation or other bodies who support people likely to have cardiac arrests ot through GPS

Given potential negative outcomes, should not go ahead without consent

D.3 What are your views about the proposed “opt out” process?

As above- far too broad. Could not be sure that reached all of potential participants-would have to be a very large and expensive information campaign unless targeted groups as suggested above.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary

because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

Seems like one of the worst examples of unethical research

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

Risks to individual such that must be their decision- benefits uncertain. Consents from whanau should only be in life and death situations

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Rarely-general presumption should be no

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

only in circumstances where intervention is a non painful test and/or minor change in clinical managment such as urine or blood test, or drug dosage or change of medication; and with whanau/EPA approval

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Should be treated the same as verbal dissent- this is how non verbal people communicate

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- (•) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Way too open to abuse or well-intentioned assumptions of researchers.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Otherwise would question why being carried out on vulnerable people- easy option?

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ◉ No
- ○ Unsure

5.2 Please give reasons for your answer.

You are making a value judgement on behalf of the incompetent person, not putting their integrity and interests first

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
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Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Astounded this is not already the case!

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

Not sure there are any- perhaps if person has terminal or deteriorating conditions and current interventions clearly not working and proposed intervention will not have negative effects like pain or distress although it may not be any more effective than current interventions.

7.3 Please state the reasons you formed this view.

People should not be subjected to research- especially "trail and error" type without their informed consent

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

I think that unless situation is one of life and death , then if person unable to give consent, should not participate in research, unless conditions as above

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

? Provider should be consulted

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

Please specify who.

Possibly persons lawyer (especially if no EPA)

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA or welfare guardi
2 Family/whanau
3 Provider not involved in
4 Other
5 reseracher

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Incompetent people should be treated the same as competent With organ donation, we may regret that more people do not indicate on their licenses that they wish to donate or agree to do so, to benefit others but that is their right. Family/whanau can give consent but that is after death.

There is too much potential for (well meaning abuse) if no-informed consent permitted in case studies outlined in this document and diminished respect for the dignity of the incompetent person.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 5 April 2017 at 12:21pm | Completed on 5 April 2017 at 2:20pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

It would be for the benefit of myself and others in the future

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

As previous question answered.we all must have some trust that the right thing will be done.

B.3 What are your views about "delayed consent"?

That's fine if patient were to wake up fully cognicient and the refused information to go forward

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

If this research were to help me and others later I cannot see it being harmful.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ○ No
- ◉ Unsure

D.2 Please give the reasons you formed this view.

Tricky one this! If adrenaline started my heart but salt water didn't what would be the next step if I was on this trial?ie if I was on the placebo .more information needed.

D.3 What are your views about the proposed “opt out” process?

Complicated. Would you be offering this only to people who had previous heart problems or the general population?

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- (●) Yes
- ( ) No
- ( ) Unsure

E.2 Please give the reasons you formed this view.

If parents were to give consent.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ( ) Yes
- ( ) No
- (●) Unsure

E.4 Please give the reasons you formed this view.

A recent television UK documentary about Down's syndrome from a parents point of view was very thought provoking about the general or perceived view that DS pregnancies should be terminated versus letting DS children / adults be who they are. We might all look to a drug that improved our brain function!!

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes generally otherwise no progress would be made in medicine

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

One would presume that there would be research committees and panels of experts that would all have to agree to any research.
Parents are asked for consent for seriously disabled children and that's ok until 21 so who decides after that.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Once again if the right laws were drafted and research was conducted under strict guidelines I can't see any problems

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- ( ) No
- (•) Unsure

2.2 Please give reasons for your answer

A professional analysis of the persons understanding would have to be carried out

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ( ) Yes

- ○ No
- ◉ Unsure

4.2 Please make any further comments you have about question 4.1.

Wouldn't this depend on the research? If it was concerning persons with a disability and not able bodied then the research would have to be carried out on the disabled group

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

First there would be no harm done

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Answered previously

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- ( ) No
- (•) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

First no harm done.. panel of experts to assess any disadvantages..

7.3 Please state the reasons you formed this view.

I'm still unsure here but as the parent of a yr old with severe disabilities and who is completely dependent on us we would have to know what research was to be carried out and we could consent or otherwise I presume but for a person with no relatives or under state care we we would want to know that thorough investigation and a group panel would have to decide.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- ( ) No
- (•) Unsure

Additional comment.

Quite frankly I'm not sure what the law exactly is.
For example,as it stands now as the parent of a yr old who is unable to give consent am I NOT able to speak for him?

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

It's very hard as a non expert to think of all scenarios here but if we were asked to consent to research carried out on our disabled son then we would want all research thoroughly over viewed by specialists and those with his best interests at heart.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

In some circumstances cultural differences mean family can override the persons original consent.eg organ donations

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

Please specify who.

Surely a panel of competent experts could decide and common sense would prevail!!!

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Specialist panel

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Family
2 Welfare guardian
3 Expert panel
4 Scientific "judge"
5 Researcher

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

In general the privacy act has gone too far and common sense should prevail in most circumstances .If consent is required of a person unable to do so then family along with clinicians and research panel experts can be left to make the best decision without causing harm to anyone.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Please feel free to contact me to clarify any thing.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 6 April 2017 at 1:48pm | Completed on 6 April 2017 at 3:03pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ◉ No
- ○ Unsure

A.2 Please give the reasons you formed this view.

No,as you would have a power of attorney,EPA, to speak for you.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ◉ No
- ○ Unsure

B.2 Please give the reasons you formed this view.

No consent means no consent,EPA,or power of attorney,have legal representation for you interest.

B.3 What are your views about "delayed consent"?

No consent means no consent, power of attorney,and EPA,are the ones who represents you interest,well being.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ○ Yes
- ◉ No
- ○ Unsure

C.2 Please give the reasons you formed this view.

This is a condition,that needs to be assessed,Dementia, will be a major epidemic come2025,2030,you would need the family,power of attorney,EPA,consent,before any research is under taken.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

You need consent,from when you first come into hospital.

D.3 What are your views about the proposed “opt out” process?

Strong NO!.should not even get to this stage.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

Why should a certain group of people be singled out. The

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

No,because you need the law to protect the vulnerable person,as well as some times this is the only time when these people need the law to protect them.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

No,taking the right away from the person (laws) EPA,and the power of attorney are in this position to represent,protect,the individual concerned.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

Taking advantage of a individual who is vulnerable the law is more apparent now.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Why have a law,if this law does not protect vulnerable people.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

The code of conduct

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- (•) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Why is there a need for change?when we have a code of conduct and now the vulnerable person act..

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ( ) Yes

- ○ No
- ◉ Unsure

4.2 Please make any further comments you have about question 4.1.

Not sure how to answer this.First there should not be any research done on any individual as consent has not been given.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ◉ No
- ○ Unsure

5.2 Please give reasons for your answer.

No consent given,no research.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ◉ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	Consent first.
2	Consulting with Maori E
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

A human rights, code of conduct,ethical?

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

you still need the consent from person who represents the individual.

7.3 Please state the reasons you formed this view.

The person who is doing the assessment,how do you know that the assessment is correct?.who or why would you believe what the assessor's has done?.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

The law needs to clarify in detail,what is and what is not.To add to the vulnerable person act,so that no individual is taken advantage of.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [x] Other

Additional comment.

To be the voice NB of the individual.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [x] Other

Additional comment.

To be the voice of the individual

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
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- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
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Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
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- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPA
2 Family
3 Doctor
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

To protect the individual from harm,or being taking advantage of,to adhere to the laws of New Zealand.

Please state your name

Organisation (if applicable)

Age care.

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

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Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 6 April 2017 at 4:01pm | Completed on 6 April 2017 at 4:23pm

Health and disability research involving adult participants who are unable to provide informed consent

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In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ◉ No
- ○ Unsure

A.2 Please give the reasons you formed this view.

A person before they get to this stage of care, should sign a document that states if they want to be part of research (done when the person is of sound mind). I don't think it's appropriate to do any form of research on a person if they have not given consent. That is why the consumer code of rights was formed to protect consumers.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ◉ No
- ○ Unsure

B.2 Please give the reasons you formed this view.

I would not want to be part of research. Before I got to this stage, I would want to sign a document to state if I would like to be involved in research in the future.

B.3 What are your views about "delayed consent"?

I would question if this is lawful. You give consent after the fact, it doesn't make sense at all.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ○ Yes
- ◉ No
- ○ Unsure

C.2 Please give the reasons you formed this view.

A person before they get to this stage of care, should sign a document that states if they want to be part of research (done when the person is of sound mind). I don't think it's appropriate to do any form of research on a person if they have not given consent. That is why the consumer code of rights was formed to protect consumers.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

A person before they get to this stage of care, should sign a document that states if they want to be part of research (done when the person is of sound mind). I don't think it's appropriate to do any form of research on a person if they have not given consent. That is why the consumer code of rights was formed to protect consumers.

D.3 What are your views about the proposed “opt out” process?

Stupid. Consent should be given when a person is not unconscious. A person shouldn't have to worry that if they don't have a bracelet which states 'no study'

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

I think it would taking advantage of someone who may not have the intellectual capacity to understand what they are entering into.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

Family should have EPOA or guardianship. Some families can be exploitative over their relatives. So decisions should be made by someone appointed by the courts

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

A person before they get to this stage of care, should sign a document that states if they want to be part of research (done when the person is of sound mind). I don't think it's appropriate to do any form of research on a person if they have not given consent. That is why the consumer code of rights was formed to protect consumers.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- (•) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Delayed consent does not feel lawful to me.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ◉ No
- ○ Unsure

5.2 Please give reasons for your answer.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ◉ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

research shouldn't be carried out at all if consent can not be obtained

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- (•) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ◉ No
- ○ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☐ Consulted by decision-maker
- ☑ Power to veto consumer's participation in the research
- ☑ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ◉ No
- ○ Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where family or whanau is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☑ Power to veto consumer's participation in the research
- ☑ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ◉ Yes
- ○ No
- ○ Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where a provider not involved in the research is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA
2 Family
3 other
4 researcher
5 provider

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 7 April 2017 at 1:25pm | Completed on 7 April 2017 at 2:19pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

Should improve care for all future patients (including me if I am unlucky enough to strike the same problem again). No incremental risk to me, or impact upon the care that I receive

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

No problem, as long as there is true clinical equipoise

B.3 What are your views about "delayed consent"?

Delayed consent is OK in principle here, with caveats. Firstly, not many patients have greatly enhanced cognitive capacity early after neurosurgery. Secondly, withdrawl of consent by a non-representative small patient cohort might skew the study results (fortunately very few patients would decline consent, in these circumstances)

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

Potential gain for me and society. Minimal risk to me. However, I would want my next-of-kin to be informed of the study, and be happy for me to participate

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (•) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

There has to be a mechanism to rigorously evaluate new treatments for cardiac arrest

D.3 What are your views about the proposed “opt out” process?

Complete waste of time. There is little likelihood of a public information campaign engaging more than a tiny fraction of those at risk (and almost no informed and rational consumer would elect to opt out)

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ○ No
- ◉ Unsure

E.2 Please give the reasons you formed this view.

Lot of grey zones here.
1. Degree of capacity of each individual with Down to give consent
2. Magnitude of likely benefit
3. Magnitude of incremental risk, especially of something as devastating as suicide

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ○ No
- ◉ Unsure

E.4 Please give the reasons you formed this view.

Likely varies case by case. Probably not, across the board

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes. No other way to improve treatments in these clinical circumstances

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

In general, comparisons should be of treatments/ strategies which are established in relevant, analogous clinical settings. There should be genuine clinical equipoise between treatments. Prospective, informed consent from next-of-kin should be impracticable

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Whether the researcher is a provider is largely irrelevant to these these issues

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- ( ) No
- (•) Unsure

2.2 Please give reasons for your answer

Very difficult to determine whether someone of reduced competence is expressing concern about participation in research, or about something else that is happening to them

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

No other option, particularly in time-critical treatment

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

In general yes - should be done in competent persons first. However, in some circumstances there might be specific reasons why the study is best undertaken in incompetent persons - though likely very exceptional

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

Important to balance the risk/ benefit. The incremental risk to the individual (from being allocated to one or other treatment arm) must be considerably outweighed by the potential benefit to others

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ◉ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	those with same condit
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

This type of research needs strong safeguards. Ethics committee oversight should be a mandatory part of this process. DSMB monitoring is also important

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

Risk/benefit to participant
Potential benefit to others/society

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

What is an EPOA - need to avoid jargon!

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1
2
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Very much depends upon the particular circumstances - who is available, clinical urgency etc

Final comments

9. Please add any final comments or suggestions you wish to make.

This only addresses part of the issue. Should comparative effectiveness research of low-risk systems-of-care be possible without prospective, individual informed consent? Not possible under current NZ law, but a major impediment to quality improvement in a learning health system

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

No concerns re confidentiality of my submission

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 15 March 2017 at 11:38am | Completed on 7 April 2017 at 3:02pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

Because the treatment options are no different to the usual procedure, participants would not be disadvantaged. Although participants cannot give consent – valuable data would be collected to help others. Within this case study patients would be provided with antibiotics and dialysis regardless, so the collection of data to improve treatments would be of benefit to all sepsis patients.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Both products have been clinically approved so comparison about safety and effectiveness would be of value. A head to head study is appropriate in this case because both drugs are already on the market and widely used by surgeons and so they are deemed safe. Use would be determined by random allocation and so one group will not be favored over another. As to the issue of informed consent, in this case patients would not care what they got as long as it worked. Clinicians would like to know which product has the edge over the other in certain circumstances, this has the potential to benefit future users.

B.3 What are your views about "delayed consent"?

Delayed consent would be meaningless if involved with a placebo intervention. The opportunity to withdraw from the study at any time should be inherent throughout the research.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

Regardless of the research, the person would be receiving conventional care. If I was in Group 2 there may be a risk of finding some of the additional contact distressing, if there was a procedure for identifying and minimizing distress if/when it occurs than this could be a safeguard.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ○ No
- ◉ Unsure

D.2 Please give the reasons you formed this view.

The risk of the side effects for the drug seem high, although without a clinical trial there may never be a body evidence developed to support the use of the drug (or not) in relation to the population under investigation.

D.3 What are your views about the proposed “opt out” process?

There is a risk that participants will not be aware of the opt out process. As cardiac arrest is not necessarily a predictable event, (in terms of when and where) the patient is likely to be distressed and may change their mind in “the moment” even if wearing the “no study” bracelet

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

On the one hand you could argue that this drug would make the participants better off than before, but the risk of suicide and other unknown side effects is high, and even if the drug was successful at improving cognitive function. That the drug would not be available after the trial begs the question of what the point is of even embarking on such a risky trial. Inclusive information about the possible risks and side effects of the drug for those without Downs's syndrome would be needed. The effect of drug is temporary so possible benefits minimal. Study should include only those capable of providing consent

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

It depends is family/whanau have legal authority to do so.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes:
In Case 1 & 2 here where they are not being disadvantaged or given different treatments to what is already available in clinical practice and where parameters are being measured quantitatively and are no different to the normal routine. If guidelines protect participants, and if there is no other way to collect the data, in certain cases the benefits of the research might outweigh the risks.

No:
Where there is a risk of harm to the patient or as in Case 3 where measurements are being taken qualitatively in a situation where these things are not easily judged because the participant is not fully capable.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

If there is no other way to collect the data and clear guidelines are understood by researchers

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- ○ Yes
- ○ No
- ◉ Unsure

1.4 Please make any general comments you have about question 1.3.

Need some examples of academic research in this area to make a judgement.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ◉ Yes
- ○ No
- ○ Unsure

2.2 Please give reasons for your answer

Facial expression, behavioral cues etc need to be recognised as dissent, and intervention stopped.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ◉ Yes
- ○ No
- ○ Unsure

3.2 Please give reasons for your answer.

Only if participation in the research is in the best interests of the participant and they are not disadvantaged in any way.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (●) Yes
- ( ) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

This should be an essential element in research design.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- (●) Yes
- ( ) No
- ( ) Unsure

5.2 Please give reasons for your answer.

Principle of do no harm is important here. Interests of patients need to take precedence over the interests of science and society. Research should entail no foreseeable risk or only a minimal risk (Scotland's provision). Research into cause and treatment of specific problem related to participant group but should not be disability specific (e.g. Ok to include someone with Down Syndrome who has cancer in research for cancer treatment). Maybe best interest criteria should be limited to observational studies only, to reduce risk of experimentation on vulnerable groups.

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- (●) Yes
- ( ) No
- ( ) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

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Any others?

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Safeguards and protects participants.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- ( ) No
- (•) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

If research were to be permitted to proceed without the consent of adult incompetent participants, then there needs to be guidelines on what criteria/tests should be used to assess the advantage and disadvantage to the participants.

7.3 Please state the reasons you formed this view.

It is unclear who defines what the best interests are of an adult who is not competent to give consent.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes

- ○ No
- ◉ Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ○ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- Yes
- No
- Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- In all cases where family or whanau is available?
- Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- Consulted by decision-maker
- Power to veto consumer's participation in the research
- Provide or withhold consent on behalf of the consumer
- Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- Yes
- No
- Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- In all cases where a provider not involved in the research is available?
- Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)

- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1
2
3
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8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 7 April 2017 at 2:54pm | Completed on 7 April 2017 at 3:44pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

If it can help people later on with the same condition then I would not mind my blood and urine being used for this research. This is probably the only way that this information could be gathered.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

The research does not appear to be extra to what I would be getting anyway and it may show that 1 treatment is safer and more effective than the other.

B.3 What are your views about "delayed consent"?

I think delayed consent should only be for observational research, not invasive research that changes the treatment people would receive.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ( ) Yes
- (•) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

Even though I agree that interactive care is best and that too many rest homes only offer task oriented care, i don't like the idea of some people being offered task oriented care if they are used to something different, just to see how it affects them. That could be mean and distressing.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

Salt water is not going to help people in cardiac arrest is it? Unless there is something else that we know can also help people (that we could then compare against adrenaline), I don't think this test is ok. If people are given salt water and they die (when they possibly could have been saved) families will be very angry.

D.3 What are your views about the proposed “opt out” process?

Hardly anyone would actually wear a bracelet just in case this happened. Not having a bracelet on would not mean people consented. It would just mean those wearing it didn't consent.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

Down Syndrome is an ordinary consequence of human diversity. People do not need to be cured. Also, the right to informed consent is vital for people with learning disability as these rights are violated too often. We need to expect more from researchers/ medical professionals in terms of how they interact/ view disabled people.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

caregivers are not the people who should be making this choice. Nothing about us without us.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Only non-invasive, observational research. Otherwise, No. The right to informed consent is too precious to trifle with.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

As above. Only if observational/ non-invasive and it will not change the treatment or comfort of the people involved.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Absolutely.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

People communicate in more ways than just verbal. It is imperative that everything is done to make sure people's wishes are respected and listened to. It is too easy to abuse those who do not speak.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- ( ) No
- (•) Unsure

3.2 Please give reasons for your answer.

Only for treatment that one would be receiving anyway. Results of monitoring is ok. Not changed treatment to see what happens.
Also, only for people who will be able to give informed consent after they have recovered.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ○ No
- ◉ Unsure

5.2 Please give reasons for your answer.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ◉ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

As an additional safeguard.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- ( ) No
- (•) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- ( ) No
- (•) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where an EPOA or welfare Guardian is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where family or whanau is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ◉ No
- ○ Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where this person is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1
2
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 9 April 2017 at 8:54am | Completed on 9 April 2017 at 11:06am

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

ONLY under the condition that I would be given exactly the same treatment as I would receive if I was not in the study. In other words, they could proceed as they would otherwise and record the results for the study but nothing else.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ◉ No
- ○ Unsure

B.2 Please give the reasons you formed this view.

It is hard to believe that the products were not carefully tested and measurements of effectiveness made BEFORE that product was allowed to be used on the public. I strongly disagree with testing products on people who can not consent to this.

B.3 What are your views about "delayed consent"?

Real "Consent" requires that it be given before the fact. Otherwise it is not "consent", it is acceptance of that which can not be undone. "Delayed consent" is NOT consent.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ○ Yes
- ○ No
- ◉ Unsure

C.2 Please give the reasons you formed this view.

As I am not a person with dementia, I can not answer for those who are. And I should not be asked to answer for them. The only person other than the patient who can give consent would be the one with healthcare power of attorney for that patient.

A better approach might be to study ALL of the patients with severe dementia in the rest home who are receiving traditional task oriented care and then add psycho-social aspects to the care of ALL severely demented patients and measure any changes.
An important aspect of such a study would be the recognition that every patient is a unique individual with varying needs and tolerance for social interaction, whether suffering dementia or not. How much interaction and what kind of interaction would benefit individual patients really has to be ascertained on an individual basis.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

Absolutely not! How can it be that, "Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully." It should be fully tested BEFORE becoming a routine treatment. Go back to the lab. If you need human subjects willing to risk their lives for the sake of research, get the GP to ask the patient for permission to be part of the study in the event that they ever have a cardiac arrest.

D.3 What are your views about the proposed “opt out” process?

That would bias the study. Most of us are not willing to wear a medical bracelet "just in case". If anything you could get those willing to opt in to risk their lives for the sake of a study to wear an opt in bracelet.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating

suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

What parent would agree to their child being a guinea pig for a drug that has already been shown to increase the incidence of committing suicide, especially since a positive effect would only be temporary? No! This is nothing short of exploitation.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

See above. It could be that false hope is given to parents and the negative side effects played down for the sake of the research (and the drug company).

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes. Only when treatment would be exactly as it would be for patients not involved in a study and only when all that is required is permission to use the measured results as data for the study.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

In no other circumstances than those mentioned above

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

The Health And Disability Commission is there to protect the rights of patients, including all those who are disabled even when they are not currently being "treated" as patients.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

They should not have to be visually distressed before their rights are returned to them. There should be NO testing (other than measurement of data from normal treatment being included in the study)without without consent, full stop.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- (•) No
- ( ) Unsure

3.2 Please give reasons for your answer.

"Consent" after the fact is NOT consent

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ○ Yes
- ◉ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

No loop holes. No consent = no testing

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ◉ No
- ○ Unsure

5.2 Please give reasons for your answer.

No one has any right, ever, to sacrifice the rights of an incompetent individual for the benefit of others.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1
2
3
4

5

Any others?

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

I do not think they should ever have the right to conduct research on an adult who can not give consent (other than including data from normal treatment in their study). If the decision is to allow testing without consent to go ahead, then at the very least the person should have the protection of an ethics committee protecting their rights above the benefits to others, including to the researchers

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

I don't think it should be permitted without consent. No loop holds. Do the tests on people who can consent

7.3 Please state the reasons you formed this view.

No one has the right to determine what is "best" for another without that person's consent or the consent of a parent or one with legal healthcare power of attorney. Even, as mentioned earlier in
this survey, when there is an emergency, we all have the right to wear a Do Not Resuscitate" bracelet or have a living will that directs what we would want.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ○ Yes
- ○ No
- ○ Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ◉ Yes
- ○ No
- ○ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☑ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

If the person appointed a power of attorney while still able to make an informed decision, then he or she has given the right to decide to that person. Parents of minors have that right. No court appointed guardian should have that right when it comes to enrolling the person in their care in a study.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☐ Consulted by decision-maker
- ☑ Power to veto consumer's participation in the research
- ☑ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

The person with power of attorney should BE the decision maker, not simply consult with some other decision maker.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

I understand that in some cultures it is customary for the family to have the right to decide on behalf of a family member, even if the patient has a living will and specifically asked for something else. It is that patient's right to decide (while able to do so) if they wish to follow that custom or not. The individual's human rights should supersede that of family or any others. If there is no such living will then the family has the right to decide, just as they would have the right to decide whether or not to continue extraordinary means to maintain life.

Additional comment.

It is NEVER the right of the researcher or the medical professional to make that decision, although they can certainly argue for the benefits

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

If there is no living will and no power of attorney for healthcare, then family ARE the decision maker.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?

- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

The provider should be available to advise family or the person holding power of attorney. He or she should have no decision making power or be involved in any way other than as advisor. If there are no decision makers available as described in previous answers, then there should be no enrolment in a study

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Advisor only to person with decision making power on behalf of the patient's wishes (eg POA or family)

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ○ Unsure

Please specify who.

The only other "part to play" is to explain or advise. NOT to decide for someone who can not decide for him or her self and has no family or appointed POA to make that decision on his or her behalf.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Advisor. Counsellor. Support.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Person appointed by pa
2 Family/whanau
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

This is not the right of the provider or researcher or any other person or organization

Final comments

9. Please add any final comments or suggestions you wish to make.

I expect the HDC to unwaveringly protect my human rights as a patient or disabled person unable to make decisions for myself. There should be a greater effort to get everyone to legally appoint a Power of Attorney to act on their behalf in the case that they can not make a decision for themselves - especially as people age. Parents of intellectually disabled children should set up a POA for when their child becomes an adult. Those from cultures that give the family the right to decide on their behalf can simply make that clear in their POA assignment.

Please state your name

Organisation (if applicable)

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If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for protecting patient rights

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 10 April 2017 at 1:43pm | Completed on 10 April 2017 at 2:21pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

The research is observational and carries no risk to the participant even though they do not directly benefit from it.

There are indirect benefits from taking part. When we enter a hospital for treatment we receive evidence-based treatments that are known to work. This knowledge is created and improved continuously and occasional research such as this should be seen as an ordinary part of treatment, especially in a tertiary hospital. Research, even simple observational studies such as this one is also one of the drivers for clinical excellence in hospitals and there is evidence that such hospitals achieve better outcomes for their patients. It is only a small step more invasive than audit, which is now a compulsory part of practice for maintenance of medical registration.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

This is basically a comparative-effectiveness study of two approved products. Which product is used may currently depend on physician preference, cheapest price tender or best marketing, all processes that need to be informed by formal studies which compare the effectiveness of products. There is no denial of the patient's right to treatment and while the study may not carry any direct benefit to the patient, it also carries no known harm.

I believe such studies should include documented discussion with the patients next-of-kin or power of attorney as part of the consent procedure. This is to ensure that taking part is in accordance with their wishes and consistent with how they believe they would respond if able to give consent personally.

B.3 What are your views about "delayed consent"?

Delayed consent is important to ensure the process is transparent. The ability to withdraw from a study at any time ensures that the study does not become a burden to the patient and that all relevant people have been fully informed

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (●) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

The study is reasonable, there is no denial of the right to treatment and it is very unlikely to be harmful. Without such research this group of patients will become therapeutic orphans, a lack of studies looking at ways to improve the treatment and quality of life of such patients is also ennervating on staff and does makes it difficult to maintain medical standards long-term. It can also be seen as a part of continuous quality improvement as it often sets newer higher standards of care.

Consent should include discussion with family or care givers to ensure such research only undertaken if they believe the patient would have consented were they able to. Written consent from their Attorney or approval of next of kin to include the patient in the study should also be obtained.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (●) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

There is no denial of the right to treatment for cardiac arrest. Current success rates are not particularly high indicating that therapy can be improved and there is trial evidence to support the study.

Before proceeding with such a study, an independent risk analysis should be obtained. The study should have a high level of data monitoring including AE/SAE reporting and be continuously monitored by an independently appointed Data Safety and Monitoring Committee.

D.3 What are your views about the proposed “opt out” process?

The opt-out option is cumbersome but necessary to ensure that there is no suggestion that the study is being done covertly. Again, such studies are how medical progress is made and an essential element of a public hospital system that strives for continuous improvement in outcomes.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor

the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

The study can be conducted in patients that are able to consent. Its efficacy should be established first before extending the drug to a non-consentable group of adults. An established part of ICH GCP is that at the end of a study a therapy should be provided free of charge to all participants (both placebo and treatment arms), if this is reasonably possible and it has been found to be effective. NZ conforms to ICH GCP according to the Medsafe website and so this guarantee of continued availability of an effective treatment should be established before proceeding.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

Consultation with family/whanau/caregivers is an essential part of such research and should definitely be done. It ensures there is no suggestion of covert research being done.
They should be able to decline participation. The initial approach to them should not be from the researcher but from a valid care giver such as treating physician or primary nurse

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

I believe the current situation in NZ is an unintended consequence of legislation designed to cater for those able to consent for themselves. The NZ ethical framework fails to fully recognize the role of family/whanau/caregivers in the treatment of such vulnerable patients. I believe the current framework including the Bill of Rights and HDC Code of Patient Rights was written without consideration of the issues raised by patients who are unable to consent. ICH GCP (current version E6) refers to consent from patients or their legally acceptable representative. This seems a reasonable position. The codes of practice from various similar jurisdictions in the appendix essentially lay out procedures for such groups of patients and appear reasonable, we should create one for NZ.

Patients accept research as a part of modern medicine that has brought significant benefits to the health of societies and frequently consent to research that is more likely to benefit society than themselves as individuals. The situation should be no different for vulnerable/demented patients, but the procedures for obtaining consent and monitoring these studies needs to be clearly defined

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

The principals for such consent procedures should have additional components, including that they are
A. Open and transparent, the patients family/whanau/caregivers must be informed and involved in the process, they are usually able to interpret how the patient would have responded were they able to give consent. ie no suggestion of some experiment being done in secret.
B. Avoid any coercion or excessive persuasion, this can be ensured by the initial approach regarding the study being made my someone not directly involved in the research (such as the patients primary caregiver). They should also witness the consent form being signed.
C. The ethics committee should also seek independent expert review of the protocol if the therapy is a novel one.
D. Have a higher level of oversight, such as the use of an independent ethics committee (not one appointed by the institution in which the study is being done such as appears to be the situation at University of Auckland currently) and independent data monitoring committee if there is a novel therapy involved.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

The ethical issues raised are the same as above. There is also a need for approval and oversight to be given by an ethical committee that is independent of the institution doing the research.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- (•) No
- ( ) Unsure

2.2 Please give reasons for your answer

This should only be a principal to be considered by ethical committees. For initial consent it may be reasonable, but for withdrawal of consent during a study, patients may wax and wain in their enthusiasm and there may be a need to observe patients for a period before withdrawing the patient

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (●) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Otherwise non-consentable patients such as with a serious illness or acute trauma become therapeutic orphans if we do not strive to improve their outcomes.
The delayed consent procedure ensures the study never becomes a burden to them. My above comments regarding more elaborate consenting procedures are relevant here also

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (●) Yes
- ( ) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

Yes, but there needs to be some reasonable test here. Research in general is carried out on the groups most likely to benefit so that if a therapy works it is found to be effective without studying very large numbers of patients –which makes the research expensive and potentially risks failing to see a benefit when it exists because of low event rates.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- (●) Yes
- ( ) No
- ( ) Unsure

5.2 Please give reasons for your answer.

yes, but only if it relates to the condition that the patient has that prevents them giving consent. This is no different from when patients able to give consent do so for a study that may not directly benefit them. It is the very basis of the randomised trial and the huge benefits that modern medicine have brought to society by constantly seeking therapies that genuinely work.

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- (•) Yes
- ( ) No
- ( ) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	The research relates to
2	That it is the best way o
3	That the patient may be
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

It is essential that all research is open and transparent. This was the issue leading to the National Womens Enquiry and the situation is no different for patients unable to give consent.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

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7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

Low risk research such as comparative effectiveness studies, epidemiological studies, questionnaires etc should be OK. They still help improve care of this patient group. They also improve the quality of care in the administering institutions and are often little more than an extension of audit (ie setting standards that can then be measured over time rather than seeing whether you attain a certain standard)
If there is a new therapy, it should not lead to the withdraw of current treatment in any material way.
It is important that therapies that may help these patients are tested, as already mentioned, the consent procedures should be much more rigorous.

7.3 Please state the reasons you formed this view.

Otherwise important research could not be done in this country

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

Considration to the appointment of an appropriately trained person appointed by the ethics committee to oversee such studies eg an ethicist or lawyer should be given also

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? *Please select all that should apply, or provide comment below if you prefer.*

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Consider also
Family and Whanau
Appointee of ethics committee
Health Care Provider
Researcher

Additional comment.

Activated EPOA's are very rare

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

Please specify who.

Appropriately trained person appointed by the ethics committee to oversee the study eg an ethicist or lawyer

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA or guardian
2 Family/Whanau
3 Provider not involved in
4 researcher

5

8.5 Please provide any other comments you wish to make about the decision-makers.

Only very rarely would it be appropriate for the researcher to provide the consent

Final comments

9. Please add any final comments or suggestions you wish to make.

It is vital that vulnerable groups of patients are studied. Otherwise they become therapeutic orphans. Current legislation does not make sufficient allowance for the many low risk studies that can help improve both treatment of patients and the quality of care in institutions looking after them. In effect, current legislation can stand in the way improving patient care for these patients.

I am surprised the document makes no mention of ICH GCP (E6) (International Conference on Harmonisation – Good Clinical Research Practice). This was originally an agreement between The USA, EU and Japan but has been ratified by many countries including NZ. Although created to ensure consistent standards for drug research the issues dealt with are universal to all practice and research. They use the term Legally Acceptable Representative as a catch-all phrase. I would like to see better guidance as to how the phrase should be interpreted in NZ.

The use of a Power of Attorney is a problematic area. In my experience, even if they exist, they are rarely activated. My hospital also has no protocol for how I should validate them when they are presented. They are mentioned by Lawyers and Commissioners, but this displays little understanding of current reality in NZ.
We also have an initiative for advanced care directives. These should include a section on research. Again when vulnerable/trauma patients present to hospital we have no way of knowing they exist, who holds it or what it says. This needs to be fixed. Surely they should be available on-line (with a gatekeeper).
There is a need for a greater role for family/whanau in decision making, in my experience they do appear to act in the interests and desires of the patient. There is a danger in over reliance on professionals and commissioners in the consent process.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 11 April 2017 at 3:53pm | Completed on 11 April 2017 at 4:16pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

My view is that I were a patient with sepsis the only hope that I would have of surviving is from the clinicians caring for me having access to evidence based medicine e.g. antibiotics and dialysis. The only way that evidence based medicine is available is by patients in previous years having been in research. I would want to contribute to the increasing body of knowledge so that if/when my children develop sepsis we are further ahead and they have an even greater chance of surviving.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Its great that I will have the option of neurosurgery that can cure me; this wasn't available 100 years ago. If I and others participate in research then in the future the care will even better.

B.3 What are your views about "delayed consent"?

I agree with delayed consent. If we only do research on conditions that allowed informed consent at the time then acute conditions will not have an evidence base to inform their best treatment.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

Patients with dementia should have the same right to research that might improve the prognosis of the condition as patients who are fully cognisant and aware. In general, I believe that people in research studies have better outcomes than people not in research.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ○ No
- ◉ Unsure

D.2 Please give the reasons you formed this view.

Depends if animal studies have shown that adrenaline is not effective and maybe harmful. If this is the case then yes we should do this study. Otherwise we should do the animal study first.

D.3 What are your views about the proposed “opt out” process?

Waste of time.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- (●) Yes
- ( ) No
- ( ) Unsure

E.2 Please give the reasons you formed this view.

It would be a great step forward if this drug was shown to be effective, worth the potential risk of side effects.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- (●) Yes
- ( ) No
- ( ) Unsure

E.4 Please give the reasons you formed this view.

It is to be assumed that they would have the patients best interest at heart.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes, to further medical knowledge in these patients. If research is not done in these patients then the medical care will not improve. It could be me or my children in 20 years time who will be benefit from this research, therefore I would be happy to participate now if necessary.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

The research must go through rigorous peer review. It must be research that has the potential to make a difference to medical knowledge.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- (•) No
- ( ) Unsure

2.2 Please give reasons for your answer

We might all screw up our face when having a blood test; that doesn't mean that we don't agree that it should be done.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

The other options are to not do the research at all or to do the research without consent and still include participants who have said they don't want to take part; both not good options.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

The incompetent participant may well be benefitting themselves from research that was done in the past on individuals who did not benefit directly.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ◉ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- ( ) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- Yes
- No
- Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- In all cases where an EPOA or welfare Guardian is available?
- Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- Consulted by decision-maker
- Power to veto consumer's participation in the research
- Provide or withhold consent on behalf of the consumer
- Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where family or whanau is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ○ Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where this person is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Family/whanau
2 EPOA/welfare guardian
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 12 April 2017 at 8:52am | Completed on 12 April 2017 at 11:18am

Health and disability research involving adult participants who are unable to provide informed consent

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In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

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This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

I don't see it as being likely to cause any harm, and the benefits to wider society (and myself in future if I end up with the same problem again) are significant. Doctors are taking things from my body and putting things into my body all the time in that situation, and I would be more than happy if they were learning from me in the process to help others.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Both products are proven to be safe so I don't see what the difference is - I am going to get one of the products anyway so really it makes no difference to my care, and in the process other people will benefit.

B.3 What are your views about "delayed consent"?

I think it's kind of ridiculous - what happens if the person wakes up and says no? In my understanding, consent by definition has to be given prior to or during an event, it cannot be given after the fact.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

The benefits seem quite high for the participants (and all dementia patients) and the risks quite low. If we know that people are in distress regularly and for long periods of time, how is it the ethical option to not try something different that may provide benefit?

I am assuming that there would be a robust ethics process for this, and that the participants would be able to withdraw if they were indicating distress at being involved in the project. There are many different ways to say no, and I have yet to meet a person who cannot in some way indicate when they are unhappy about something.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ○ No
- ◉ Unsure

D.2 Please give the reasons you formed this view.

This one is tough and I really can't decide how I feel about it. It seems that whether we do it or not, the risks to people are quite high. But I also think that it is crucial that we get the information about whether it works or not.

D.3 What are your views about the proposed “opt out” process?

Again I am unsure. I imagine that there are people who would want to opt-out but not want to wear a bracelet, as that's a little bit like telling the world you have heart issues and many people will not want this.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

Any medication which risks causing depression and suicidal ideation is in my opinion extremely high risk, and should not be used unless it is essential for the person's health and well-being. I do not see that increased cognitive capacity is essential for a person's health or well-being.
People with Down Syndrome (and other cognitive impairments) are ill-treated in our society and I do not think the appropriate response to our ill-treatment of people is to make the person take a pill to make them more 'normal'. Similarly, we know that many gay people are ill-treated in our society, but I do not think that the appropriate response is to give them a pill (harmful or not) to make them straight.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ◉ Yes
- ○ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

Although I am strongly opposed to this particular study, I believe that many people with profound learning (intellectual) disabilities would benefit from research which seeks to improve their lives, and I do not believe the ethical option is to deny people the right to have research which improves their lives.

Again I am assuming there would be a robust ethical process to go through. We would need to seriously consider who has the right to consent on behalf of a person - I am uncomfortable with the idea that a paid caregiver can give consent on behalf of a person (unless they are like a foster parent for a person who has no strong family connections).

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes I do believe it should, as there are many situations where we would gain invaluable knowledge that benefits us which we could not otherwise obtain. For instance, as I stated earlier, I don't think it is an ethical choice to deny people with profound learning (intellectual) disabilities any opportunities to be involved in and/or benefit from research.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

As much as possible the people around the person who know them well should be involved in the consent process, as they will know whether the person is likely to be OK with the research, and will know when the person is indicating they are

unhappy with the research or in distress.

I believe we must have robust ethical processes for all health and disability research. For disability research in particular, I believe that disabled people (and perhaps family/whanau) should be involved in the ethics process, so that the mantra of "nothing about us without us" is fulfilled. Many researchers can be quite disconnected from the communities they are researching and having disabled people and family/whanau involved would potentially highlight issues that a researcher would not have thought of.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- ○ Yes
- ○ No
- ◉ Unsure

1.4 Please make any general comments you have about question 1.3.

Given the restrictions of the current law, I would be unhappy for academic research to fall under the law (because then people with profound disabilities would never benefit from research).

Any non-academic research should absolutely fall under the Code.

If the law was changed to enable research with people who cannot give consent, then I would be happy for all research to fall under the Code.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ◉ Yes
- ○ No
- ○ Unsure

2.2 Please give reasons for your answer

Absolutely. If a person is expressing dissent or refusing to take part, this is their way of saying they do not consent and we must respect this.

However, we we would need to be wary that a person wasn't removed from the research just because they were having a bad day on one day - some days a person may consent and some days they may not, and we should work with this.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ○ Yes
- ◉ No
- ○ Unsure

3.2 Please give reasons for your answer.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes
- ( ) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- (•) Yes
- ( ) No
- ( ) Unsure

5.2 Please give reasons for your answer.

We all live with the significant benefits because of the risks that other people have taken in the past so we can gain knowledge, and I see no problem with carrying this forward. How are we to make improvements for the benefit of everyone if we don't do this?

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ( ) Yes
- ( ) No
- (•) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Absolutely, this is a critical factor for me. I would only be happy for the law to change if this was in place. Without robust ethics processes we cannot ensure that the research will be done in the best way possible, and we cannot ensure that all steps necessary have been taken to ensure participants won't be harmed.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

The research must be trying something that seeks to reduce harm, provide benefits to people, or gain knowledge which is for the advancement of the community of people involved in the research. I recognise that 'gaining knowledge' is very broad and this is intentional, as I think we can really limit ourselves by needing to prove that knowledge has an immediate benefit. Obviously this needs to go through robust ethics processes and have the lowest level of harm possible.

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

I don't think that researchers or paid support people should be allowed to make the final decision about whether a person is involved in a study or not - I think an advocate (such as family/whanau) should be making this decision. If there are no appropriate family/whanau to make a decision, perhaps an independent advocate who knows the person well could decide (I am wary about denying people with profound disabilities who have no family connections the opportunities to be involved in research which could benefit them).

In medical emergencies where a person cannot consent and immediate action must be taken, an ethics committee needs to decide if it is OK for this to happen.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

As much as possible the participant's will must be sought through the entire process. I consider consent to be an ongoing process, and people should be able to indicate interest or dissent throughout the process and be able to withdraw at any time.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ◉ No
- ○ Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where a provider not involved in the research is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

Please specify who.

Many disabled people do not have family in their lives, and I am concerned that this group would be denied the opportunity to participate in and benefit from research if only EPOA's, welfare guardians and family/whanau can give consent. For instance, if someone was researching how strong relationships could be developed for people with profound disabilities with no family involvement. In this situation I am unsure - perhaps an independent advocate who knows the person well or who talks to the people who know the person well.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

As stated above

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA or welfare guardi
2 Family/whānau
3 Other independent advo
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

In my experience seeking ethics approval for some research, I was concerned that the ethics committee had no requirement to consult with the community I was researching with (learning disabled people).

I was uncomfortable that I was able to proceed to this stage of working with participants without disabled people being involved in the ethics process. I would like to see this incorporated into ethics processes in future, so that we can be assured that the community we are researching with have had input into the research and feel satisfied it is OK to do.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 11 April 2017 at 7:53pm | Completed on 12 April 2017 at 12:49pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

There is no change in management, and the study is an observational one.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Both products are already in use without strong evidence that one is superior than the other, so the patient could be getting either product anyway even if they weren't in the trial.

B.3 What are your views about "delayed consent"?

Fine in this context.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ( ) Yes
- ( ) No
- (•) Unsure

C.2 Please give the reasons you formed this view.

Next of kin or the person with POA should be used to consent in this case.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

The omission of adrenaline in cardiac risk challenges a cornerstone of cardiac arrest management.

D.3 What are your views about the proposed “opt out” process?

Seems reasonable

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

The potential side-effects seem quite significant.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ○ No
- ◉ Unsure

E.4 Please give the reasons you formed this view.

The family/caregivers may have an ulterior motive, especially when caring for a disabled child.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes, where others have power of attorney or if the study is an observational study that doesn't affect clinical decision-making.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

As above. Restrictions should apply when there is risk of significant harm to the patient.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ( ) Yes
- ( ) No
- (•) Unsure

2.2 Please give reasons for your answer

A mechanism has to be in place to validate those expressions. A nod is easy to understand, facial expressions less so.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

If the study is unlikely to pose significant risk to the patient

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ( ) Yes

- ○ No
- ◉ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ◉ No
- ○ Unsure

5.2 Please give reasons for your answer.

Hard to balance the lack of consent with no possible benefit to that person.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

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Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- Yes
- No
- Unsure

6.2 Please give reasons for your answer.

Not if it's just on observational study, for example - in which case institutional review should be sufficient

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- Yes
- No
- Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- Yes
- No
- Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- Yes
- No
- Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where an EPOA or welfare Guardian is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where this person is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA
2 Family
3 Provider not involved in
4 Researcher
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 12 April 2017 at 2:32pm | Completed on 12 April 2017 at 2:58pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

If I could help doctors know more about effective treatments I would do it

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

As a neurotypical person I would be fine about contributing in this way, however I would not presume to speak for people who have disabilities or injuries.

B.3 What are your views about "delayed consent"?

I would be fine about "delayed consent" BECAUSE I personally would give consent. Probably someone who does not want to give consent would not be okay about delayed consent.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ( ) Yes
- (•) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

I feel that my family would care for me so I would not want to interact too much with paid supports

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

Does not sound safe. CS tells me I would rather have the adrenaline and would rather my paramedic knew exactly what they were dealing with.

D.3 What are your views about the proposed “opt out” process?

Not sufficent as most people would not go so far as to apply for and wear this bracelet

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

Very bad history of people with disability being tested on medically. People with DS should be celebrated for who they are, not drugged into changing.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ○ No
- ◉ Unsure

E.4 Please give the reasons you formed this view.

I think a person can be asked, can your family/whānau/caregivers consent for you? If yes then okay to proceed.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes, sometimes the benefits outweigh the risks

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

For myself as a neurotypical person I would generally consent, if I was incapacitated in my consent then I would still like the opportunity to contribute. In my case my family would be there to interveine if the study was going to be detrimental to me. For others without these privilages I dont think that the same should apply

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Otherwise they could miss out on valuable information

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- No
- Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- Yes
- No
- Unsure

5.2 Please give reasons for your answer.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- Yes
- No
- Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

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Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- Yes
- No
- Unsure

6.2 Please give reasons for your answer.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- Yes
- No
- Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- Yes
- No
- Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- No
- Unsure

Additional comment.

Supported decision making process should be investigated before subtitude decision making

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where an EPOA or welfare Guardian is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [x] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

Please specify who.

Disabled Persons Organisations (DPO's) in an advocate capacity.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Family/whanau
2 EPOA/WG
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

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Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

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Started on 12 April 2017 at 5:56pm | Completed on 12 April 2017 at 6:24pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

Non-invasive testing that will help others. Go for it.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Both products are currently seen as equally safe, so why not.

B.3 What are your views about "delayed consent"?

As long as the procedures have no impact on my health outcomes or level of care... and isn't too invasive. I'm ok with it

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

As both approaches currently have similiar outcomes, either is fine. However, if my family/key contacts had strong views on this I think they should be heard, as it's very hard to watch someone go through this... having some sense of control over the type of care I receive may help them cope a little better.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (•) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

It would help agree the right medical approach to take, with very little risk to me - OK

D.3 What are your views about the proposed “opt out” process?

In this case it's not a practical option to opt out. The bracelets, in context, are likely useless as its unlikely you're hear about or prepare for the study & even if you were you wouldn't be in a position to make a decision with a clear head

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ○ No
- ◉ Unsure

E.2 Please give the reasons you formed this view.

I don't understand Downs syndrome well enough, would want research done with some people with the condition... to help determine a risk/return framework. To help balance the pro's & cons from their perspective.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

I'm uncomfortable with the assumption that caregivers have a genuine interest in people in their care - due to personal experience

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes - However, there does need to be careful checks & balances around this especially in cases where the research is invasive, or there are cultural implications.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

Particularly for conditions/cases where this is a real barrier to research, or there is a significant public health interest.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- ○ Yes
- ○ No
- ◉ Unsure

1.4 Please make any general comments you have about question 1.3.

I don't know anything about the current laws

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ○ Yes
- ○ No
- ◉ Unsure

2.2 Please give reasons for your answer

Depends very much on the person's condition & general context. For example, someone with dementia may look distressed at all kinds of things.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ◉ Yes
- ○ No
- ○ Unsure

3.2 Please give reasons for your answer.

Only in specific cases

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ○ Yes

- ○ No
- ◉ Unsure

4.2 Please make any further comments you have about question 4.1.

Don't want all the of the research funds to go here, however, evidence should be provided that this has been considered and there are compelling reasons for researching a vulnerable group.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

Public health reasons, or the wellbeing of other people with the condition etc... should be considered.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ◉ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	Potential to improve qua
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Always. There is obvious potential for abuse if not. For both patients, institutions and researchers, this check needs to remain in place.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- ( ) No
- (•) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- ( ) No
- (•) Unsure

Additional comment.

I don't know enough about the law & the roles people play

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

What is an EPOA?

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☑ Consulted by decision-maker
- ☑ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where family or whanau is available?
- ☑ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☑ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ◉ Yes
- ○ No
- ○ Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where a provider not involved in the research is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☑ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Family/Care-er

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA or welfare guardi
2 Family/whānau
3 the consumer's respon
4 Researcher
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

NA

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

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Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 13 April 2017 at 11:13am | Completed on 13 April 2017 at 11:37am

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

Because you would be given the same medicine and it wouldn't affect the outcome, I am happy with information gathering for general betterment of outcomes

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

Because information gathering where there is no harm to the patient is ok by me

B.3 What are your views about "delayed consent"?

This is a good thing as the patient can have a chance to have a say and have their data removed if they wish

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ( ) Yes
- (•) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

Because I think that there would be enough patients that were able to consent to participate

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

Because it feels too invasive

D.3 What are your views about the proposed “opt out” process?

I dont have confidence that public awareness campaign would be effective and that the 'No Study' is a decision that people want to make prior to it happening to them.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

People with down syndrome have enough 'testing' already and I would be concerned about the side effects already known are too great let alone the ones they dont know about. I think that there are greater alternatives to improving cognitive and learning than with medicine.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

It is unfair to place family in this position and would not necessarily be reflective of the patient's wishes

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

If the treatment is not amended and only information, data and follow up is needed then I am happy if the patient can't consent and if there is a 'opt out' at a later date if applicable. If it changes the treatment plan and involves side effects and becomes a 'guinea pig' approach then informed consent is needed.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

As above.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- ( ) No
- (•) Unsure

3.2 Please give reasons for your answer.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ○ No
- ◉ Unsure

5.2 Please give reasons for your answer.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

I am not sure

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- ( ) No
- (•) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☑ Consulted by decision-maker
- ☑ Power to veto consumer's participation in the research
- ☑ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where family or whanau is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☑ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ◉ No
- ○ Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where a provider not involved in the research is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Family
2 GP
3 Welfare Guardian
4 Other
5 Researcher

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 13 April 2017 at 12:49pm | Completed on 13 April 2017 at 1:34pm

Health and disability research involving adult participants who are unable to provide informed consent

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In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ◉ No
- ○ Unsure

A.2 Please give the reasons you formed this view.

I would not like people to be taking blood off me when I have not consented, and where there is no benefit to me.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ◉ No
- ○ Unsure

B.2 Please give the reasons you formed this view.

I would rather that my consultant use the product he usually uses

B.3 What are your views about "delayed consent"?

Not a fan - too little too late

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ○ Yes
- ◉ No
- ○ Unsure

C.2 Please give the reasons you formed this view.

I think this research is invalid as each carer works differently and it would not be possible to control for this. Most carers do provide for psychosocial needs, where possible but the staffing levels mean that physical needs - feeding, cleaning, - take precedence so even if this theory was shown to be valid, nothing would change anyway.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

If I had a cardiac arrest, I would not want a placebo to be administered

D.3 What are your views about the proposed “opt out” process?

Sounds unworkable to me

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ○ No
- ◉ Unsure

E.2 Please give the reasons you formed this view.

MAy be of some use to participants.

Why is it now called Down Syndrome when it was always Down's Dyndrome

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ○ No
- ◉ Unsure

E.4 Please give the reasons you formed this view.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Generally, no, as it should be a decision made by the person concerned.

However, there may be rare cases when the research is looking at something that is so important that it may be necessary - I think this is better dealt with by the Courts

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

That is their decision and should be respected as such

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- (•) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ○ No
- ◉ Unsure

5.2 Please give reasons for your answer.

Only after a Court gives permission

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ◉ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- ○ Yes
- ○ No
- ◉ Unsure

6.2 Please give reasons for your answer.

i would prefer a high Court decision

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ◉ Yes
- ○ No
- ○ Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ○ Yes
- ◉ No
- ○ Unsure

Additional comment.

I would prefer a High Court decision

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☑ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

An EPOA or Welfare guardian should be involved/consulted but not the final decision-maker -depends on the issue

Additional comment.

i do not want to see these people used as guinea pigs, as happened with groups of people before - eg, people with Syphilis, in the state in the 50s

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☑ Consulted by decision-maker
- ☑ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Depends on how well the provider knows the consumer

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

Please specify who.

Can't think of anyone but would not rule it out

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 other
2 EPOA
3 Family
4 provider
5 researcher

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Would like to see more research on EPOAs and when they are invoked and what happens when the person is no longer incompetent

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

I would not like my name published - if I had known this at the beginning, I may not have done the survey - I may have missed this aspect.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 13 April 2017 at 2:32pm | Completed on 13 April 2017 at 4:31pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

If I was that unwell I would want others in my situation to benefit in the future. The harm done to me by blood testing and urine analysis would be insignificant. I may even benefit as if I was part of a trial I might even get more attention.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

If I were facing such a dreadful thing as brain surgery, I would absolutely want to be part of a trial that might even incrementally improve outcomes for others. If no trial has already been done, then I am randomly taking a chance anyway, based on surgeon's preferences. Far better to know one way or another, if one product is better than another. As I am a Kantian, I have a duty to pursue knowledge, so as I would be no worse off by contributing, I would give consent (if I could!)

B.3 What are your views about "delayed consent"?

Not impressed as it is not comparable to prior consent. If you survived and did well, against all odds, you might feel compelled to give it retrospectively, even if things happened to you that you would not normally consent to. I feel that there could well be an element of coercion which would be hard to eliminate. It also feels like a patient is asked to give forgiveness for being experimented on. It should be that doing a procedure is stand alone morally acceptable, irrespective of what the patient says later.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

Dementia is such a terrible and basically untreatable irreversible and hopeless condition (I am the sole carer for my -year-old father with dementia) that any treatment with even a remote chance of helping would be something I would consent to. This trial has all the appearances of being a positive experience for the participants, and even if some did find the extra interactions distressing, getting dementia in and of itself is distressing.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (•) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

and it is imperative that evidence-based medicine is based on hard evidence. If you have a heart attack and need adrenaline, something has already gone horribly wrong anyway. Some of the historically accepted treatments in vet medicine have been found to be harmful when put under the lens of scientific analysis, so it is better to know.

D.3 What are your views about the proposed “opt out” process?

Very against opt out. This idea presupposes we all have the ability to make a positive effort to do so.

So some sections of the community, especially the disadvantaged would be disadvantaged. And why should the opt-outers be made to wear a stigmatising bracelet? Others in society might ridicule them.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

There is already a group who are able to give consent, so I would think that group should be trialed first and consider the harms done in a group able to express wishes.

Suicidal feelings are a terrible harm, even in just enduring them before they get to a point of action. If people are unable to give consent, they are probably unable to articulate or understand feelings. So those non-consensual people might be feeling all the bad emotions with no way of articulating themselves and saying they wish it to stop. That would be pretty heinous. So there seems here a reasonable risk of some members suffering a terrible side effect which has no easily measurable proxy marker. If it were something organic, such as kidney failure, you could do a legitimate blood and urine panel, but here it is just a feeling of misery, with no way of knowing its strength.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

Because the possible side effects are not easily or objectively measurable, and the consequences of failing to measure misery appropriately might be catastrophic, it is too much of a responsibility to put on family members. Also, if you live with such a thing I could imagine your desire to help others could overwhelm your objective assessments, so being depressed in a non-consensual person might be put down to "a bad day" when it could, in fact be a serious depressive episode.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes, because otherwise we will never have any objective research on the most vulnerable members of society, those who are critically ill, or with diseases of cognitive impairment which threaten the essence of self.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

If the risk of harm is small, and the chance of benefit is real, it should be allowed. If there is no other way to make rapid evidence-based advances in knowledge. If the disease is life threatening, untreatable and catastrophic, especially in cases such as dementia, where the disease is occurring in old age for the most part, so even a death in that situation is not as much of a harm as it would be in a 20-year-old with full cognitive awareness.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (●) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Without making any sweeping generalizations, I have met a few neurosurgeons and neurologists, and on the whole, they tend to be very able to totally objectify the patients. Some of the research they have asked to do on humans seems pretty inhumane. I have seen some ethics committee applications for research. So they can get easily blinded to a remote chance of a good outcome, and override patient rights. So we need to have everyone subject to the same laws.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (●) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Autonomy is the most important aspect of people's life, and the default position should be any doubt and the procedure should stop.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- (●) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Too open to coercion, and too consequence driven. The consent process should be justifiable on its own. So it should be about is it right, not about how things turned out. It also feels like the patent is expected to be complicit in something they had no part of.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ○ Yes
- ◉ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

I am not sure that would be a coherent request. If you are studying sepsis patients, who are in ICU, the drugs used on them may well be unlikely to ever be used on a fit and well competent person. And being hooked up to a life-support system is going to so fundamentally alter bodily parameters, comparisons may not be useful. So some diseases will by nature mean there are no consenting members. All people with that disease will be nonconsenting. The competent verses noncompetent seems less of an issue than risk and outcome and life expectancy. Drugs used on non-consensuals generally have a history of being used elsewhere, and there is pharmacological prior knowledge, so those issues are more important that ensuring a trial on competent patients first, as I could see how this might end up delaying or wasting funding for really urgent serious treatments.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

If you have a disease, or condition which causes you misery and suffering, then it is natural to not wish that on others, and natural to wish to try and help prevent or treat it in others.

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ◉ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	similar condition
2	similar ethical beliefs (
3	gender-eg helping othe

4	inciting causes-eg peo
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

All animal research is required to go past an ethics committee, so it would be consistent to do so for humans who cannot give consent,

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

Severity of the disease and present outcomes. If most people die from a disease as it is presently treated anyway, then we might allow a greater risk of possible disadvantage in trial treatments.
If there is no hope of recovery, the outcome is horrible, and the person at the end of their natural lifespan, higher risk treatments are acceptable.
If the person is unconscious, as in ICU, and they cannot experience any discomfort pain or distress, we can do a lot more to them that we could to say a dementia patient who may not understand but still be able to feel fear and not want interventions.
If the possible harmful outcomes are possibly very bad, but unmeasurable, such as suicidal feelings, that would be a reason to not to trial a drug. Harmful outcomes which can be anticipated, measured and the drug stopped might be tolerated, however.

7.3 Please state the reasons you formed this view.

I think the idea of consent needs to be broader and include likely good to the individual, and to society. A lot of people would willingly risk some harm, especially if reversible, for a chance of a greater good. If you are at the end of your life (my father often says he wants to be used for experiments!) you may well be happy to be part of a do or die trial about dementia. Vegans are often happy to be experimented upon if it saves animals, so some people would find some harms acceptable. So if autonomy is the most important aspect of a person, and we value that, autonomy will not always be best served by do no harm.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

EPOAs should be able to give permission to be enrolled in a trial.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? *Please select all that should apply, or provide comment below if you prefer.*

- [x] In all cases where an EPOA or welfare Guardian is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

There are some situations where ethical beliefs are really important to the patient.
I am a vegan, and I would never accept animal products such as a pig heart valve, even if that meant I were to die. If I was unconscious I would want someone to prevent that happening to me.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. *(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)*

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

An EPOA however, is someone you choose! Unlike your family!
I went to a palliative care lecture and the doctor there was saying 75% of his requests for euthanasia came from the family, not the patient. I do not think genetic links give anyone moral power over your life.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

A GP should always be involved, as they are an outside objective and informed observer, and it adds a layer of protection for the patient.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

Please specify who.

I think a lot of people with strong ethical beliefs, such as animal rights activists, have a stronger bond with other activists that they do with their own family.

A lot of us are willing to be experimented on in order to provide good non-animal based evidence based research. So my colleagues in animal rights would be much better placed to make decisions for me than my family.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA
2 Provider not involved GP
3 Other-close friends
4 researcher
5 family

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Encouraging people to make advance directives would be a good thing here. Considering people's life style and ethical choices also are important in considering what sort of choice they would make for themselves.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 19 April 2017 at 11:27am | Completed on 19 April 2017 at 1:49pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

I do not consider that urine and blood tests are invasive or harmful to me if I have sepsis. Although this research may not benefit me personally, it wouldn't harm me either.

I would only ask that any urine or blood taken would be disposed of after the research and not redistributed or held onto like the HeLa cells were.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

The text states that both products have clinical approval and are currently used by surgeons. If one were approved and one were not, or if one caused me more physical harm and one did not, then I would not want the procedure done.

B.3 What are your views about "delayed consent"?

I don't see the point in delayed consent. Of course people should be (and to the best of my knowledge ARE) able to have their data removed from the study if they wish, but presumably it is non identifiable so I wouldn't have a rationale for requesting my data be removed.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

This could be a case where family could consent on behalf.

We have all known someone with dementia of some kind and I would support any move to increased psychological care, contact and personhood for these individuals.

If participants are having a bad day or find additional contact distressing, they should not be forced to participate any further, but be welcome to join back in with the group if they wish.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

I understand the need to study this to test whether we are giving people the best chance of survival, however this is a situation that could cause harm to me and hinder my recovery. As discussed in the group setting by the HDC and Associate HDC, I wouldn't accept this level of risk for myself or my loved ones.

I also think the trial could be distressing for paramedics, who presumably are in that job to save lives not compromise them with salt water.

D.3 What are your views about the proposed “opt out” process?

I support opt-out process's in some medical settings such as organ donation, however I do not think the reach of the opt out campaign would be good enough to include older people at risk of heart attacks that may not be familiar with the process of opting out.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

There is insufficient evidence about the effectiveness of the drug on cognition.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

I do not think proxy consent should be available in this case. There are other, less invasive supports with more of an evidence base to increase cognition in individuals with down syndrome such as education and learning aids.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

I believe that right 7(4) is restrictive in that the individual must benefit. I believe if the individual is not harmed, then in most cases (and I would defer all cases to an independent committee for review) an individuals consent should not be needed.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- ○ Yes
- ○ No
- ○ Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ○ Yes
- ◉ No
- ○ Unsure

2.2 Please give reasons for your answer

Children do not like going to the dentist or getting injections, but it benefits them. If the same can be shown for research, then it should go ahead.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ○ Yes
- ○ No
- ◉ Unsure

3.2 Please give reasons for your answer.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes
- ( ) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

Or it should be shown that it will not cause more harm to a vulnerable group than a competent group.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- (•) Yes
- ( ) No
- ( ) Unsure

5.2 Please give reasons for your answer.

But only if it does not cause them harm or pain

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ( ) Yes
- ( ) No
- (•) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1
2
3
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5

Any others?

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

if the procedure is not in their 'best interests' but does not cause harm, then it should be allowed.

This view of harm throughout my submission is not intended to be a naïve view in this submission, I know that the word 'harm' is very subjective.

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes

- ○ No
- ○ Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ◉ Yes
- ○ No
- ○ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where an EPOA or welfare Guardian is available?
- ☑ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☑ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☑ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Only when the individual cannot give consent for themselves, and only if it does not cause the individual harm

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

I do not believe family should be able to veto a decision if a person has stated that wish prior to becoming incompetent.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)

- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

There is merit in involving a persons clinician, they presumably know the persons medical history well and are an independent decision maker (in the sense that they are outside of family ties and have no interest in the outcomes of the study)

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [x] Other

Additional comment.

power to make recommendations about whether the research harms the person unable to give consent - or conflicts with any of their pre existing conditions

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

Please specify who.

People close to the person unable to give consent should be able to weigh in, but ultimately the decision should lie with an independent review committee.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA/guardian
2 family
3 responsbile clinician
4 researcher
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Researchers should not have any sway whether people give consent or not, they have a vested interest and may be unable to be objective.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

Individual submission

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 19 April 2017 at 11:04am | Completed on 19 April 2017 at 2:40pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

The research would do no harm to me as the patient.
The principle of distributive justice, in relation to sharing of risks and benefits, can be applied here. What is learnt from my participation will benefit others in the future, and perhaps even me in the future if the same circumstances arose for me. This principle is often described in Europe as the solidarity principle, where it can be important to look beyond the immediate benefit to an individual and consider the greater benefit to all of society, from the proposed research. This principle can be easily applied if there is minimal or no risk of harm to the participant, and should not be negated by excess consideration of the autonomy principle. Balanced considerations should apply.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

For the same reasons as outlined in case study A.
In addition, in this case, both products are approved for use, and without such research, clinician preference or judgement could be the sole deciding factor in which is administered. in my view, this brings forth an imperative that research is conducted to see which is better and for which patients. The regulatory regime should not set such high thresholds that might prevent such studies, where no harm is expected, and where absence of research could lead to future harms through less knowledge.

B.3 What are your views about "delayed consent"?

I am surprised that this would be considered important. Yes to informing patients of what was done and explaining the reasons for it. But providing for withdrawing data from the study seems an extreme application of the autonomy principle, in this example, where no harms are expected or likely, and where the data may provide good benefits to all future patients, and potentially to that patient in future too. While I note that this is a right that all study participants currently have under the code, I think there is an implication that it is there for the protection of personal and sensitive data, rather than for data about medical benefits and harms.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes

- ○ No
- ○ Unsure

C.2 Please give the reasons you formed this view.

As per answers to cases A and B, such research should be permitted, as there seems to be an absence of likely harm. In this case there is also likely benefit to the patient, so it could be argued that the research may in fact (possibly) be in the patients best interest.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ○ No
- ◉ Unsure

D.2 Please give the reasons you formed this view.

This case is more difficult to discuss with certainty about the best response. I'm not familiar with the arguments for and against adrenaline in such cases.
I think the question should be one for an ethics committee to decide, based on the level of uncertainty about the best procedure to follow, and what need there is for such research, the likely harms and benefits to study participants, and to future patients once the study produces answers.
The description suggests that perhaps adrenaline use is current best practice, and at first glance many people might be resistant to inclusion in a study that potentially gives a placebo instead. But there seems an assumption in the research proposal that adrenalin might in fact produce harms that are not well understood. Thus the research becomes important towards understanding what the best care is. My view is that this is a more complex question than can be effectively assessed by individual consumers regarding participation in such a study. A randomized and placebo controlled population study would seem the only way of determining the answer, but there would need to be very careful consideration by an ethics committee whether the uncertainty in current practice, and the risks and benefits to participants and future patients, would make such a study acceptable.

D.3 What are your views about the proposed “opt out” process?

It is very unlikely to be a practical or workable option. A better approach would be to conduct consultation or focus groups among patients at risk of future cardiac arrest, as part of the ethics evaluation process. It is likely this would give some clear directions about the acceptability of such a study.

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor

the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- (•) Yes
- ( ) No
- ( ) Unsure

E.2 Please give the reasons you formed this view.

What is not stated in the case study is (my understanding) that if the study drug is currently approved but for other indications, then a registered medical practitioner would be allowed to prescribe off label use in patients with Down syndrome, as part of their license to "practice the art of medicine".
If that assumption is correct, it shifts the paradigm in relation to this case study, and argues strongly of the need for research to determine the risks and benefits of the drug for those with Down syndrome.
The principles of solidarity and distributive justice, as described earlier, provide a good counter-balance to a narrow focus on autonomy and consent, in this case. Furthermore, there is potential direct benefit to participants and to future patients if the drug is found to be beneficial, and the avoidance of harm if in fact it is found to have no benefit or produces some real harm.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

E.4 Please give the reasons you formed this view.

My experience (parent of with an intellectual disability that is not Down syndrome) including extensive interaction with parents and other caregivers of those with such disability, is that families and caregivers have a very strong investment in the welfare and well-being of the disabled person and will provide a very strong protective consideration to any research that is proposed for them.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes.
For reasons of:
Solidarity.
Distributive justice in the sharing of benefits and risks.

Potential future benefits apply also to some participants as well as the future patient population.
The study process may provide benefits (as well as harms) to the participants.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

A caveat I would suggest, is that approval of such studies has an emphasis on expectations of low or minimal expectations of harm to participants, or a very strong need for the research because of considerable uncertainty about what best practice should be for such patients.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- ○ Yes
- ○ No
- ◉ Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- ○ Yes
- ○ No
- ◉ Unsure

2.2 Please give reasons for your answer

This looks an attractive qualifier to any such study, but it is probably far too simplistic. For example, my daughter's level of disability and anxiety about invasive procedures means she will almost certainly say NO to any procedure, even when of clear benefit to her.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ○ Yes
- ○ No
- ◉ Unsure

3.2 Please give reasons for your answer.

I think this issue may be a bit of a red-herring. If the study is well planned and approved according to suitable standards, including those I referred to in answers to the case studies, then the process of informing the patient after the event should be seen as a matter of respect for them and keeping them fully informed, rather than one of consent.
But current provisions do provide for withdrawal of consent at any time, which they can exercise a they see fit. But note my earlier comment about that being implicitly about personal and sensitive dat, and less likely to be aimed at statistical data as one in a group.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- ○ Yes
- ○ No
- ◉ Unsure

4.2 Please make any further comments you have about question 4.1.

This has an attractive "first glance" look to it, but life is much more complicated isn't it.
when considered from the perspective of groups of patients who are generally unlikely to be competent to consent, it might simply add another level of complexity to the approval process, for little actual protection or benefit to the target group.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

1 - because it may benefit them.
2 - because it may benefit others too.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes

- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- ◉ Yes
- ○ No
- ○ Unsure

6.2 Please give reasons for your answer.

A very desirable level of protection for such participants and an ideal way to ensure that the proposed study meets the threshold that makes such research acceptable.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

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7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ○ Yes
- ◉ No
- ○ Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

Level of uncertainty about current practice that justifies the study.
The seriousness of the condition under study.
Balance of potential benefits and harms to the participants.
Balance of potential future benefits gained and future harms avoided, for other patients.

7.3 Please state the reasons you formed this view.

The reasons are based on a balanced application of the 4 part framework of Beauchamp and Childress, providing for autonomy, avoiding harms, doing good, and distributive justice.
The evolution of the HDC code in NZ has had a very strong emphasis on autonomy (consent). this remains very important but there are many instances where this can be better balanced with a variety of other important principles.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ◉ Yes
- ○ No
- ○ Unsure

Additional comment.

Not sure if it needs a law change to give effect to it. Some things can be done by regulation (e.g. Code changes) or by adapting ethics requirements for study approval. But overall I think this is an important area that would be best done at a high level such as regulation (code change) at least, if not a law change.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ◉ Yes
- ○ No
- ○ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? *Please select all that should apply, or provide comment below if you prefer.*

- ☐ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

This discussion is problematic for me. Most families do not have EPOA or welfare guardianship in place. It is expensive and cumbersome to set up for those where intellectual disability is involved. In our case we have not done this, instead relying on a process of supported decision-making throughout our children's lives. This has admittedly become more problematic as our daughter has developed dementia and we may need to go down the WG track now, under the PPPR act.
However we feel marginalised by the lack of reference to "next of kin" or significant others who represent the interests of the person. Our role should be no less important in such cases as those where the EPOA or WG role has been formalized. We are their advocates, and our role should be recognised and accepted in health and research issues for them, just as it is in banking, welfare benefits, etc.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

See comments relating to EPOA and WG in previous question. The role of family or next-of-kin advocates should have recognition just as those other roles do.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where a provider not involved in the research is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Perhaps, where no EPOA, WG or next-of-kin advocate is available.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☑ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where this person is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Cannot contemplate at this point who those "others" might be.
In addition, and this comment applies to the three previous pages too, I think that check-box 2 above gives a confused message about studies versus health interventions. "saving the consumer's life or preventing serious damage to the consumer's health" sounds to me like an individual healthcare intervention, not a research study, and governed by different criteria such as best practice, medical ethics in emergency care, etc.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1
2
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

I think this question confuses consent with enrolment. The patient or their advocate/EPOA/WG holder gives consent to enrolment. The researcher decides on entry criteria about whether to enroll the person, or not, once consent is given.

Final comments

9. Please add any final comments or suggestions you wish to make.

I'd like a copy of this submission to review or amend once submitted. I don't see a "print" option. can you send it to me at please.
contact me on if you'd like clarification on any of these answers.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 19 April 2017 at 4:34pm | Completed on 19 April 2017 at 4:58pm

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

To gain information

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- (•) Yes
- ( ) No
- ( ) Unsure

B.2 Please give the reasons you formed this view.

To gain more information

B.3 What are your views about "delayed consent"?

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- (•) Yes
- ( ) No
- ( ) Unsure

C.2 Please give the reasons you formed this view.

Information

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- (•) Yes
- ( ) No
- ( ) Unsure

D.2 Please give the reasons you formed this view.

Information

D.3 What are your views about the proposed “opt out” process?

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- (●) Yes
- ( ) No
- ( ) Unsure

E.2 Please give the reasons you formed this view.

Information

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- (●) Yes
- ( ) No
- ( ) Unsure

E.4 Please give the reasons you formed this view.

next of kin

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Information

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

Provisions are made for consultation with whanau

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- (•) Yes
- ( ) No
- ( ) Unsure

3.2 Please give reasons for your answer.

gain information

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ◉ Yes
- ○ No
- ○ Unsure

5.2 Please give reasons for your answer.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ◉ Yes
- ○ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	Whanau
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- (•) Yes
- ( ) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where an EPOA or welfare Guardian is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

Please specify who.

Whanau

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [x] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [x] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Whanau
2
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

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Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

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Started on 20 April 2017 at 10:03am | Completed on 20 April 2017 at 10:57am

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

I would not be harmed by my participation.
It is likely that the blood would be drawn painlessly using already inserted devices.
Some good would come of my dire situation.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ○ No
- ◉ Unsure

B.2 Please give the reasons you formed this view.

In this case I think it is preferable to only include participants who are able to consent unless the numbers are too few. What is the rationale for including both groups?

B.3 What are your views about "delayed consent"?

This is an area that requires further thought and debate. If I was a participant I would most likely not be happy to find that I had been included in a dtudy and the only way of opting out was to have my data not incuded after the fact. Perhaps if the participants in this situation had discussed their views already with their family or EPOA that would be acceptable.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ◉ Yes
- ○ No
- ○ Unsure

C.2 Please give the reasons you formed this view.

The research is likely to be beneficial to others in the same situation in the future.
My family would be able to indicate to the researchers that this is the type of research that I would be interested in participating in.
I would expect the researchers to be sensitive to any indicators or distress that I displayed and if necessary would abandon the assessments temporarily if I became distressed

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- ○ Yes
- ◉ No
- ○ Unsure

D.2 Please give the reasons you formed this view.

Cardiac arrest is a life-threatening event. There would need to be a very convincing argument for the non-use of a current treatment.

D.3 What are your views about the proposed “opt out” process?

I would need to be very convinced that all members of the community had access to the information, that bracelets were free, that efforts were made to include vulnerable members of our community who have low health literacy and are affected by health inequalities in our society. Otherwise the study could be seen as experimenting on the disadvantaged. Additionally, the data would not be representative because people with advantages, good health literacy and most likely better health would opt out, leaving a pool of potential participants skewed towards the disasvantaged

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ○ No
- ◉ Unsure

E.2 Please give the reasons you formed this view.

People with Down syndrome who are unable to give informed consent are perhaps not likely to have expressed their views about participation in research with their families, so it is difficult to see what the families would be basing their consent on.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ○ No
- ◉ Unsure

E.4 Please give the reasons you formed this view.

As above

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes.
People who are cognitively impaired have a right to contribute to our community by participating in research.
People who are cognitively impaired have a aright to have their voices heard.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

The person who supports decision making for the person should do that based on their knowledge of what the person would have decided if they had been able to.
Participation should not harm the person.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (•) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

It is important to have consistency in approaches to consent.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

For some people who have communication difficulties related to disability or cognitive impairment, communication is by way of body language or behaviour. Those people who know the individual well are able to guide researches about how the person expresses disssent or refusal and this should be respected.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- ( ) No
- (•) Unsure

3.2 Please give reasons for your answer.

If there has been an intervention and the person then does not consent, the only option is for the data to not be included. Perhaps delayed consent could apply to non-intervention studies only.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes

- ○ No
- ○ Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ○ No
- ◉ Unsure

5.2 Please give reasons for your answer.

I think the benefits to others must outweigh the potential harm to the non-consenting participant.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- ○ Yes
- ◉ No
- ○ Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	
2	
3	
4	
5	
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

Because the potential participants are vulnerable people

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- (•) Yes
- ( ) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

The best interests test is reasonable

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- ( ) Yes
- (•) No
- ( ) Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ◉ Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- ☐ In all cases where an EPOA or welfare Guardian is available?
- ☐ Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- ☐ Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- ☐ Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- ☑ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- ( ) No
- (•) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [x] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
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- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 Family/whanau
2 EPOA or welfare guardi
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

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Started on 13 April 2017 at 11:45am | Completed on 20 April 2017 at 3:32pm

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In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

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This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

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The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

Knowledge gained could help future patients. I would want the researcher to seek informed consent from my next-of-kin, and to ask for my informed consent if I regained competence.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons. The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- ○ Yes
- ○ No
- ○ Unsure

B.2 Please give the reasons you formed this view.

B.3 What are your views about "delayed consent"?

I consider that a plan to seek delayed consent on its own is insufficient ethically and legally to justify proceeding to carry out research on an incompetent person. Of course it comes too late, as people have already been included in the research. But if the person regains capacity, their subsequent consent should always then be sought to their continued participation, and if they refuse consent, they should be withdrawn from the study, and their data removed where possible.

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- ◉ Yes
- ○ No
- ○ Unsure

C.2 Please give the reasons you formed this view.

Could lead to better care in the future, and could be of benefit to participant, but any signs of distress or unwillingness should result in withdrawal, and I?C from next-of-kin sought as a precondition.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- Yes
- No
- Unsure

D.2 Please give the reasons you formed this view.

D.3 What are your views about the proposed “opt out” process?

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- ○ Yes
- ◉ No
- ○ Unsure

E.2 Please give the reasons you formed this view.

Risks are more than minimal, and benefits too speculative.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- ○ Yes
- ◉ No
- ○ Unsure

E.4 Please give the reasons you formed this view.

I do not consider that proposed consultation with family/whanau is a sufficient protection for participants. That is what Right 7(4) currently provides. For reasons I raise la to protect subjects.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

Yes, I consider that research should be allowed to proceed on incompetent adult subjects, but that very strong safeguards are needed for the protection of this vulnerable group.

If the current law was applied strictly, most nonconsensual research could not proceed, which would mean that the development of new potentially beneficial treatments for the conditions which affect them would be significantly restricted, and incapacitated people could miss out on the opportunity to access treatments which may be potential directly beneficial to them. On the other hand, this group of subjects cannot assess the potential risks and benefits of involvement for themselves, and they must rely on some one else to do that for them. That person will not themselves be injured or harmed if something was to go wrong.

At present some nonconsensual research is proceeding. It may be ethical but is of doubtful legality, and it is proceeding without proper safeguards for incompetent people. I consider that the current position is the worst of both worlds.

Some such research has a good prospect of providing a direct individual benefit to the person, and providing the potential risks are minimal, should be able to proceed with the informed consent of a personal representative and subject to strong safeguards. I list these in subsequent boxes.

Simple amendment to the "best interests" threshold in Right 7(4) would be insufficiently protective of this vulnerable group. Right 7(4) operates as a defence to Code liability, rather than as a permissive regime with strong safeguards.

In my opinion a legally binding, detailed regime of strong safeguards is required, preferably enacted in primary legislation (such as the Protection of Personal and Property Rights Act 1988), or in additional separate Code rights applicable to this specific situation.

In particular, strict safeguards would be especially necessary and important if incapacitated people were to be included in research where there was no possible benefit to them. This is often the riskiest kind of research, and there is no compensating potential for them to benefit. Along with other protections, detailed below, there would have to be a minimal risk condition, and informed consent from a personal representative.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

1) There should be a condition that where possible, efforts should be made to gain the subject's prior informed consent to participation before the onset of incapacity, and if they are incapable of giving I/C, their informed assent should be sought. The subject should take part in the informed consent procedure as far as possible, and must be given information according to his/her capacity of understanding regarding the trial, its risks and benefits. This is required by the supported decision-making paradigm of the Convention on the Rights of People with Disabilities.

(2) The HDEC must be satisfied that the trial has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the cognitive abilities of the patient.

(3) There must be a statutory requirement for HDEC scrutiny and approval before nonconsensual research can proceed.

4) The legislation should state a principle that incompetent subjects can only be used in research when competent subjects cannot be used.

5) It should be a condition of their inclusion that the research cannot proceed unless it is connected with an "impairing condition" affecting the incapacitated subject, or its treatment.

(6) A rule is required that any evidence of a subject's dissent or unwillingness to be involved or any indication of a wish to be withdrawn results in their non-enrolment or their immediate withdrawal. eg the MCA condition is that nothing may be done to a participant to which they appear to object, such as showing signs of resistance or otherwise, unless it is necessary to protect them from harm or reduce pain or discomfort. Nor can anything be done which is contrary to an advance decision, or any other form of statement by the participant.

(7) There should be a condition that an incapacitated person cannot be included in clinical research without the informed consent of a legal representative. Since there is no legal ability for a substitute decision-maker to give informed consent on behalf of an incapacitated person at present in the law, a statutory provision would be required to permit a guardian or personal representative to give informed consent on their behalf to their inclusion in the research. This is an essential condition, but only one among others.

(8) The legislation should provide that "There must be scientific grounds for expecting that the research would be likely to produce a real and direct benefit for the individual."

(9) There should be a condition that, whether or not there is an expectation that the research would be likely to produce a real and direct benefit for the individual, the research must entail no more than a minimal foreseeable risk and minimal foreseeable burden to the participant.

(10) No incentives or financial inducements are permitted to be given to the subject or their legal representative.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- (●) Yes
- ( ) No
- ( ) Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- (•) Yes
- ( ) No
- ( ) Unsure

2.2 Please give reasons for your answer

Respect for the autonomy of the incapacitated person and well as the principle of non-maleificience supports the inclusion of conditions that (1) the incapacitated person is included in the informed consent process as far as possible, and they must be given information according to his/her capacity of understanding regarding the trial, its risks and benefits. This is desirable, as being consistent with newer approaches of supported decision-making in the Convention on the Rights of Persons with Disabilities, and also with Right 7(3) of the Code; and (2) their continuing assent is necessary, so that any evidence of objection, dissent, unwillingness to be included or to continue or to any procedure or any indication of a wish to be withdrawn is implemented without delay, unless it would be harmful to the person.

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- ( ) Yes
- (•) No
- ( ) Unsure

3.2 Please give reasons for your answer.

Delayed, retrospective consent alone is an insufficient ethical justification. They may never regain capacity to consent, & if they do, it comes too late as they have already been included in the research. It is inconsistent with the principle of autonomy, as some people will be included who never get to decide or who refuse consent. But, if the person regains capacity, it is an essential ethical requirement, based on respect for autonomy, along with the other conditions I have described, that if some one regains capacity, their informed consent to continue or to their information being withdrawn should then be sought. If not provided, they and their data must be withdrawn from the study where possible or unless it would be harmful to them.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- (•) Yes
- ( ) No
- ( ) Unsure

4.2 Please make any further comments you have about question 4.1.

The legislation should state a principle that incompetent subjects can only be used in research when competent subjects cannot be used. It should be impossible to do research of comparable effectiveness on individuals who are able to consent to participation. This is required to prevent individuals who lack capacity being used as research subjects when it would be possible to recruit competent subjects. It is a feature of all of the overseas models, EU Regulation 2015, art 31.1.(e), MCAs 31(4), AISA s 51(1).

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- ○ Yes
- ○ No
- ◉ Unsure

5.2 Please give reasons for your answer.

This question raise 2 issues

First, you seem to be asking about the "subject's condition" requirement, that the research should not be permitted proceed unless it is connected with an "impairing condition" affecting the incapacitated subject, or its treatment, and which is responsible for their inability to give an I/C. A justification for this condition is that individuals are more likely to support research on conditions from which they suffer, as it is more likely to be consistent with their preferences and interests and to identify with its goals. I think it is an important inclusion. ,

Secondly, should research on incompetent people which may only benefit future patients and society ever be permissible? This is difficult & highly contentious. There is a kind of visceral objection to the idea of researchers conducting medical experiments on people who are unable to consent, when there is no possibility that they may derive any personal benefit & the only possible benefit is to future patients. Some bioethicists (Paul Ramsey, Hans Jonas) consider that non-therapeutic experimentation on the incompetent is never justifiable, because it uses them exclusively as a means to others' ends. It makes them into a "mere object of medical experimentation for the sake of good to come," contrary to their intrinsic dignity. They really are reduced to a testing subject & are treated like an inanimate object. While I am strongly attracted to this position, I also worry that it may lead to a virtual ban on non-therapeutic research using incapacitated subjects for conditions affecting only them, where other capacitated subjects could not be used (at Phase I for example), even if there was "minimal risk" and "minimal burden" to them. Would this seriously hinder the ability to develop new treatments for the conditions affecting incompetent people?

The only way in which non-therapeutic research on incompetent subjects can be justified is to take a frankly utilitarian approach: that scientific advances in treatment or knowledge about the condition & the interests of future patients with the same condition can sometimes justify involving incompetent subjects in research of no benefit to them. I would want to know more about the issues relating to this difficult question before being convinced that the law should allow this.

If the position is taken to make it lawful in some circumstances, very strict safeguards are required as it does entail using people as human guinea pigs, to put it baldly. The Scottish Act requires that the researcher make a compelling case of significant societal benefit for conducting it. I think that some sort of provision like this would be important – that "the ethics committee must be satisfied by credible evidence that that the research will contribute through significant improvement in the scientific understanding of the adult's incapacity to the attainment of real and direct benefit to the adult or other people having the same incapacity …" Also that it cannot be done on capacitated people.

Most importantly, all three pieces of legislation (the EU Regulation 2014, AISA & MCA) deal separately with risk (physical and psychological) and burden (discomfort, interference with privacy, freedom of movement & inconvenience) & impose both minimal risk & minimal burden conditions, as well as satisfying the other conditions. Eg the MCA provides that the non-therapeutic research should be likely to benefit other members of the group to which the subject belongs, and there are "reasonable grounds for believing that the research entails only negligible risk to the participant and, in addition it must not significantly interfere with the participant's freedom of action or privacy or be unduly invasive or restrictive." (MCA).

If the answer to question 5.1 is yes:

5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- (•) Yes
- ( ) No
- ( ) Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1	Minimnal foreseeable ri
2	Minimal foreseeable bu
3	Informed consent of leg
4	No indication of dissen
5	Ethics committee appro
Any others?	

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- (•) Yes
- ( ) No
- ( ) Unsure

6.2 Please give reasons for your answer.

All overseas models require this, and it is an essential condition, required by the ethical principles of non-maleficience and beneficience. These participants cannot weigh the potential risks against the benefits and decide for themselves whether they want to participate. They requires others to do so for them, and one body (not the only) which must do this on behalf of society which derives the benefits of clinical research & so is morally obligated to protect this vulnerable group is an HDEC.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

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7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- ( ) Yes
- (•) No
- ( ) Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

The benefit threshold should be defined as follows: "There must be scientific grounds for expecting that the research would be likely to produce a real and direct benefit for the individual." This requires scientific evidence to support probable grounds for expecting that the individual will benefit from inclusion

There should always be a minimal risk and burden threshold: Whether or not there is an expectation that the research would be likely to produce a real and direct benefit for the individual, the research must entail no more than a minimal foreseeable risk or minimal foreseeable burden, discomfort, interference with the freedom or movement or privacy of the participant.

7.3 Please state the reasons you formed this view.

In respect of evidence of the potential advantages and benefits, while "is in the best interests" threshold in Right 7(4) is too high, the threshold should be stated as stated in para 7.2. This combines the wording of the Scottish legislation and the EU Regulation 2014. I think it would be the best wording on offer, as it requires an expectation of a likelihood (rather than a mere "potential" as in the MCA, s 31(5)(a)) of direct benefit, as well as an objective scientific basis for that expectation, which the HDEC would be expected to check for & check off, which I consider important to emphasise.

There should be a condition that, whether or not there is an expectation that the research would be likely to produce a real and direct benefit for the individual, the research must entail no more than a minimal foreseeable risk or burden/discomfort to the participant. I favour the minimal foreseeable risk threshold in the Scottish legislation over a proportionality principle in the MCA (s 31(5)(a)), in the case of research with the potential for individual benefit as well as that with no such prospect, because it specifies an upper limit of risk. The proportionality principle does not specify a maximum degree of acceptable risk. Despite the appearance of objectivity and neutrality, balancing the risks and benefits of research is a subjective exercise. Processes of risk assessment always involve value judgments. The potential for researcher bias, even unconscious, in favour of recruitment and the research proceeding may result in researchers taking an unduly optimistic view which may tend to downplay the risks & magnify the benefits of participation. A minimal risk condition mitigates this concern.

There are admittedly difficulties in defining the category of "minimal risk". There are various definitions on offer. The usual definition of a minimal risk standard comes from the US Common Rule: that the probability and magnitude of harm or discomfort anticipated in the research are not greater in & of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." It has been heavily criticised as the "risks encountered in ordinary life" are different for different people, & so very variable & so this definition is too flexible & uncertain. The Scottish Law Commission suggested this more objective (& therefore better) definition, which unfortunately wasn't included in the AISA, but which would be a useful addition to our legislation: "Minimal risk is regarded as covering a small chance of a trivial reaction or distress and a very remote chance of serious injury or death, comparable to flying as a passenger in a scheduled aircraft." The MCA defines "negligible burden" in s 31(6)(b)(i) & (ii).

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- (•) Yes
- ( ) No
- ( ) Unsure

Additional comment.

At present the researcher decides, based on a best interests assessment and must seek prior views of the consumer or consult (only) with "suitable persons". This is insufficiently protective of the person. They should be informed and able to participate to the extent of their capacity (assent), if unable to give informed consent, but in addition, I consider that there should be a legal requirement that an incapacitated person cannot be included in clinical research without the informed consent of a legal representative. Since there is no legal ability for a substitute decision-maker to give consent on behalf of an incapacitated person at present, a statutory provision would be required to permit a guardian or personal representative to give informed consent on their behalf to their inclusion in the research (if other conditions are also met). I favour an "informed consent by a legal representative" model, rather than a "veto" model as in the MCA. Most people, I believe, would prefer that those closest to them or, failing that, some one independent of the research, make the decision about their inclusion, rather than a researcher subject to a family member's veto. The nearest relative knows them best & is more likely to be able to accurately predict what they would want & to be the most motivated person to protect them from harm. Researchers have an inherent conflict, as they will invariably be motivated to facilitate the research to proceed, & this may affect their interactions with family/whanau. Actually placing the responsibility for the decision on the personal representative to give or refuse informed consent may encourage them to take the decision more seriously than they might if just given a veto.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (●) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where an EPOA or welfare Guardian is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

In the prior screen I stated that a condition of nonconsensual research proceeding is the informed consent of a legally designated representative (either a personal representative (closest relative) or, if unavailable, an independent professional representative such as the subject's carer or GP). The legal representative could be a welfare guardian or an EPOA.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

In answer to 8.3 I indicated my reasons for considering that a legal representative's power of veto only is unacceptable, compared to the power of the legal representative to give or withhold consent.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (●) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [x] In all cases where family or whanau is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

I envisage that the legal representative who would be given power to consent on behalf of the subject would in the first instance be the closest family member or next of kin, such as a spouse or parent or child. The AISA provision is good and seems to cover all the bases, without being too detailed: "consent has been obtained from any guardian or welfare attorney who has power to consent to the adult's participation in research, or where there is no such guardian or welfare attorney, the person's nearest relative." (s 51(3)(f)).

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- (•) Yes
- ( ) No
- ( ) Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where a provider not involved in the research is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [x] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

The MCA provides for a professional representative if there is no personal representative that can be found. This may be worth consideration, but it must be some one independent of the research. While an advantage of GPsis their expertise to be able to assess the risks and benefits of inclusion, it has been suggested in the UK that in general they may be too sympathetic towards clinical research for them to be an appropriate choice. Other options, such as lawyers or social workers, may be worthy of consideration? Incompetent people without whanau to protect their interests are particularly vulnerable.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ( ) Yes
- (•) No
- ( ) Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1 EPOA or welfare guardi
2 Family/whānau or close
3 Third party professional
4 Provider not involved in
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

(1) I now consider that the informed consent of a legal representative (nearest relative, caregiver or third party professional) should give informed consent as a precondition to inclusion of an incapacitated person, rather than merely being able to veto inclusion; and (2) I am more sceptical about whether it should be legally and ethically permissible to include incapacitated people in clinical research where there is no expectation that they could derive an individual personal benefit from inclusion.

Please state your name

Organisation (if applicable)

blish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982.

If you consider that all or part of your submission should be treated as confidential, please state this clearly below and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information.

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Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received.

The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Started on 21 April 2017 at 10:53am | Completed on 21 April 2017 at 11:09am

Health and disability research involving adult participants who are unable to provide informed consent

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, research on a person who is unable to give consent can take place only if participation in the research is in that person's best interests.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving adult consumers.

You do not need to answer all of the questions for your responses to be considered by the Commissioner.

Case Study A: Observational study measuring clearance of antibiotics during dialysis

The study

Dr A wants to study how quickly antibiotics used to treat septic patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

Dr A proposes a study involving acutely unwell septic patients in the ICU, who are unlikely to be able to provide informed consent owing to the impact of the sepsis. Dr A will not amend the treatment provided to the study participants — they would be provided with antibiotics and dialysis in the same way as they would outside of the study. However, Dr A would enrol the participants in his research and measure the changes in antibiotic concentrations during the participants' dialysis sessions. Changes would be measured by a number of tests, including urine and blood tests that would not otherwise be performed.

Information from the study would not affect the clinical management of the participants, and they would not benefit from the research. However, Dr A believes the data gathered may lead to more accurate dosing of antibiotics for other septic patients in ICUs in the future.

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

- (●) Yes
- ( ) No
- ( ) Unsure

A.2 Please give the reasons you formed this view.

This is a general statement I would use to answer all questions about observational research. Along with many others, I regularly analyse anonymous data from the Ministry of Health National Minimum Dataset and associated datasets. This is allowed under current HDEC rules, often without full ethics review. I think such research is directly analogous to the question posed here. The individuals I research do not, and in any practical sense cannot, provide consent. There is public good with no individual harm. Another situation that I think is directly comparable is the routine audits that are done daily in health services. These do not require consent because they are 'audits' to improve health services. I do not believe the line between audit and research is at all clear - they are both conducted as part of the overall quest to 'look at what we are doing to see if we can do it better'. Many of my colleagues would say that audit is work you did not anticipate publishing when you undertook the work (even if you later decide it would be in the public good to publish, which I find quite acceptable); research is work you intend to publish.

Case Study B: Clinical trial comparing two products used following neurosurgery

The study

Dr B wants to compare the safety and effectiveness of two products used to achieve a watertight closure of patients' brain membranes following neurosurgery. Both products have already been clinically approved and are commonly used by surgeons.

The current evidence does not indicate that either product is safer or more effective than the other, but no research has been conducted that directly compares the two products.

Dr B proposes to conduct a study on consumers undergoing neurosurgery, who would be randomly allocated to receive one of the two products. Dr B would then collect data about the safety and effectiveness of each product.

The consumers are mostly having surgery in relation to brain tumours and are likely to have reduced capacity to make decisions. Some of the potential participants may have brain injuries, cognitive impairments, intellectual disabilities, mental illnesses or be in intensive care. While some of the proposed participants may be able to provide informed consent, others will not have the capacity to do so. Dr B believes that both groups need to be included in the research in order to gather useful data that can be generalised to other consumers in the future.

Dr B intends to include consumers who are unable to give consent, and then seek "delayed consent" from any consumers who regain the capacity to consent after the trial. If any of those consumers refuse consent after regaining capacity, their data will be removed from the study.

B.1 If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?

- Yes
- No
- Unsure

B.2 Please give the reasons you formed this view.

B.3 What are your views about "delayed consent"?

Case Study C: Trial regarding care provided to consumers with severe dementia

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The study

Dr C wants to study the care provided to rest home residents with severe dementia. Dr C believes that conventional care for such consumers is task-focused, concerned primarily with the consumer's physical needs and daily activities. Dr C thinks conventional care may be neglecting consumers' psychosocial needs, meaning that many consumers with dementia are spending many hours alone and emotionally distressed. Dr C thinks that part of the problem may be that a dementia diagnosis is treated as diminishing a consumer's personhood, leading staff to reduce their efforts to establish and maintain relationships with the consumer.

Dr C proposes a study that would randomly allocate consumers with severe dementia into two groups, each group receiving a different type of care. Group 1 would receive conventional care, which focuses on physical task-oriented practices and physical needs. Group 2 would receive "interactive care", an alternative to conventional care that is intended to maintain personhood as dementia progresses. "Interactive care" includes a greater focus on the psychosocial needs of the consumer. At this stage, there is very little evidence about the benefits or risks associated with "interactive care". However, Dr C believes that the proposed study could supply evidence that would lead to improvements in the care provided to consumers with dementia.

It is not known whether the research would be in the participants' best interests. They would have to undergo additional assessments as part of the research, but the additional assessments could benefit the participants if the increased contact with the researchers was beneficial to them, or changes in their condition were picked up that would not otherwise have been noticed. On the other hand, there is a risk that some participants may find the additional contact distressing.

The proposed trial would take place over four months. Researchers would assess the participants' agitation levels, psychiatric symptoms and quality of life before and directly after the trial period, and then again four months after the conclusion of the trial.

The fact that a consumer has dementia does not necessarily mean that he or she is unable to provide informed consent. Some may be capable of providing informed consent with appropriate support, or they may have intermittent periods when they are able to provide consent to participate in the research. Dr C also proposes to include in the study consumers who are not able to consent.

C.1 If you were a person with dementia and unable to consent, would you want to be a participant in this research?

- Yes
- No
- Unsure

C.2 Please give the reasons you formed this view.

Case Study D: Clinical trial regarding use of adrenaline

The study

Dr D wants to study the use of adrenaline in the treatment of cardiac arrest. Adrenaline has been used as a routine treatment for cardiac arrest for over 50 years, but its safety and efficacy have not been tested fully. Several previous studies suggest that while adrenaline may help to restart the heart initially, it may also lower overall survival rates and increase brain damage. While these studies have led to significant concerns about whether adrenaline could be harming consumers, the body of evidence is not yet strong enough to change current practice.

Dr D proposes a large clinical trial to gather further information. The trial would be randomised, double-blind and placebo-controlled. This means that some of the participants would receive adrenaline and some would receive a placebo (in this case, salt water). During the trial, neither the participants nor the paramedics would know who was being given adrenaline and who was being given salt water.

No consumer undergoing treatment for cardiac arrest would be able to provide informed consent to participate in the study, so Dr D proposes to enrol consumers in the trial without obtaining consent. She considers that the research is important to ensure the best outcomes for consumers who have cardiac arrests in the future, and that it cannot be conducted on consumers who are able to provide consent.

To deal with this issue, Dr D suggests an “opt-out” process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by requesting a bracelet with “NO STUDY” engraved on it. Awareness of the study would be raised through a public information campaign.

D.1 If you suffered a cardiac arrest, would you want to be part of the study?

- Yes
- No
- Unsure

D.2 Please give the reasons you formed this view.

D.3 What are your views about the proposed “opt out” process?

Case Study E: Clinical trial of drug for people with Down syndrome

The study

Dr E wants to investigate whether a particular drug will improve the cognitive and learning abilities of people with Down syndrome. He proposes a randomised, double-blind, placebo-controlled study. This means that some of the participants would receive the study drug and some would receive a placebo (for example, a sugar pill). During the trial, neither the participants nor the researchers would know who was receiving the drug. Participants would be required to undergo regular six-hour assessment visits to check their progress.

The study drug has already been tested on people without Down syndrome. That research provided some information about the possible risks and side-effects of the drug, including that, for some participants, it increased the incidence of contemplating

suicide. However, there may be other risks or side-effects that have not yet been discovered. In particular, the effects of the drug on people without Down syndrome may be different from those on people with Down syndrome.

It is not known whether the drug will have the desired effect on cognition or learning (or any other beneficial effects). However, it is likely that even if the drug did lead to an improvement in cognition for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

Some adults with Down syndrome may be capable of providing consent if given appropriate support and information. Those consumers could then be enrolled in the study in accordance with ordinary consent principles. Dr E proposes also to enrol participants who are not able to give consent because the effects of the drug on those participants may be different. Dr E proposes to consult with family/whānau/caregivers and, if they express objections, those participants will not be enrolled.

E.1 Do you think people with Down syndrome who are unable to give informed consent should be part of this research?

- Yes
- No
- Unsure

E.2 Please give the reasons you formed this view.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?

- Yes
- No
- Unsure

E.4 Please give the reasons you formed this view.

In this part you will be asked whether you think the law should remain as it is or be changed. We would like to know what factors or criteria you think should be taken into account when considering whether incompetent adults should be research subjects, and who should be the decision-maker(s).

The **case studies** may have helped you to form an opinion about whether our existing law draws the line in the right place and, if not, where you think it should be drawn. You may find it useful to refer back to them when considering the consultation questions to follow.

Click here to view the case studies on our website.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.

1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

1.3 Do you think the same laws should apply to all health and disability related research?

- Yes
- No
- Unsure

1.4 Please make any general comments you have about question 1.3.

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?

- Yes
- No
- Unsure

2.2 Please give reasons for your answer

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

3.1 Do you think the law should be changed to allow researchers to obtain delayed (retrospective) consent to research after incompetent participants regain competence to consent?

- Yes
- No
- Unsure

3.2 Please give reasons for your answer.

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?

- Yes
- No
- Unsure

4.2 Please make any further comments you have about question 4.1.

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

- **be permitted only if it may benefit others who have the same or a similar condition to the participant**
- **be connected to the impairing condition that prevents the participants from being able to provide consent**
- **be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent**
- **be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.**

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?

- Yes
- No
- Unsure

5.2 Please give reasons for your answer.

If the answer to question 5.1 is yes:
5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?

- Yes
- No
- Unsure

5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. being the most important and 5. being the least important.

1
2
3
4

5

Any others?

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?

- Yes
- No
- Unsure

6.2 Please give reasons for your answer.

Ways to assess the advantages and disadvantages of participation by incompetent consumers in research

7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?

- Yes
- No
- Unsure

If you answered "No" to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Who decides?

8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?

- Yes
- No
- Unsure

8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current New Zealand law?

- Yes
- No
- Unsure

Additional comment.

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making.

Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

EPOAs and welfare guardians

Should EPOAs and welfare guardians ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- Yes
- No
- Unsure

If yes, in what circumstances should EPOAs and welfare guardians be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- In all cases where an EPOA or welfare Guardian is available?
- Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where an EPOA or welfare guardian is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer. ***(A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.)***

- Consulted by decision-maker
- Power to veto consumer's participation in the research
- Provide or withhold consent on behalf of the consumer
- Other

Additional comment.

Family/whānau

Should family/whānau ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- Yes
- No
- Unsure

If yes, in what circumstances should family/whānau be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- In all cases where family or whanau is available?
- Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where family/whānau is involved in decision-making, what role should they have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- Consulted by decision-maker
- Power to veto consumer's participation in the research
- Provide or withhold consent on behalf of the consumer
- Other

Additional comment.

Provider not involved in the research (e.g., consumer's responsible clinician or GP)

Should a provider not involved in the research ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- Yes
- No
- Unsure

If yes, in what circumstances should a provider not involved in the research be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- In all cases where a provider not involved in the research is available?
- Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's

life or preventing serious damage to the consumer's health.)

- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where a provider not involved in the research is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- [ ] Consulted by decision-maker
- [ ] Power to veto consumer's participation in the research
- [ ] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Other person

Should any other person ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?

- ○ Yes
- ○ No
- ○ Unsure

Please specify who.

If yes, in what circumstances should this person be involved in decision-making? ***Please select all that should apply, or provide comment below if you prefer.***

- [ ] In all cases where this person is available?
- [ ] Only when particular criteria are met? (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health.)
- [ ] Only where the circumstances require that an urgent decision is needed (see, e.g., Case Study D)?
- [ ] Only when other possible decision-makers are unavailable? (Please specify which decision-makers, below.)

Decision-makers.

Additional comment.

Where this person is involved in decision-making, what role should he or she have?

Please choose any of the options that you think should apply, or provide comment if you prefer.

- ☐ Consulted by decision-maker
- ☐ Power to veto consumer's participation in the research
- ☐ Provide or withhold consent on behalf of the consumer
- ☐ Other

Additional comment.

8.4 Who do you think should be the final decision-maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.

- **EPOA or welfare guardian**
- **Family/whānau**
- **Provider not involved in the research (e.g., the consumer's responsible clinician or GP)**
- **Researcher**
- **Other**

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5. being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1
2
3
4
5

8.5 Please provide any other comments you wish to make about the decision-makers.

Final comments

9. Please add any final comments or suggestions you wish to make.

Please state your name

Organisation (if applicable)

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