Started on 21 April 2017 at 4:53pm | Completed on 21 April 2017 at 6:57pm

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.

Clear benefit to population in general and no detriment to me as a patient

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.

Since both treatments are "commonly used by surgeons" It seems to me that the study may be redesigned as a post-treatment audit study where informed consent may be obtainable removing the requirement for delayed consent.

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

I am more comfortable with delayed consent where the delayed consent sought would not materially affect the application of treatment. It should however be seen as a 'last resort' for study design.

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 may be an impossible question to answer prior to becoming a patient with dementia as how the dementia affects you may determine whether the extra intervention distresses you or not. It might be a decision best made by enduring power of attorney - someone who knows the patient and may be able to monitor or better understand changing levels of distress in the patient.
If extra intervention causing stress is an area of concern with the study, then even the process of trying to obtain consent from the patient may be 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.

There are 'significant concerns' about harm from adrenaline. It would seem prudent to investigate these and it may not change my personal outcomes (who knows?) from cardiac arrest.

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

I assume the opt-out process was chosen because an opt-in bracelet would not recruit enough participants. I would want to be sure an opt-in option was carefully investigated and rejected for good reasons.

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 benefits of completing the study for people with downs syndrome do not seem to outweigh the risks as outlined.

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.

At the moment we rely on consultation with family etc as the 'gold standard' for consent when it is otherwise unable to be given by the patient themselves. It is the balance of risks and benefits in the study for people with downs syndrome which doesn't make it viable in my opinion.

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.

As you may be able to see from my previous answers I think it very much depends on the design of the studies and the overall perceived benefit to the population (especially the population being studied), but there are situations where the outcome of the study may be more useful overall than the risk of enrolling individuals without 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.

Where possible consent should be sought from family etc or enduring powers of attorney. Where the circumstances of the study make this impossible because the treatment being studied must be applied before any form of consent can be obtained, retrospective consent should be sought from family etc as soon as possible.

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.

Is there any reason at all why non-providers should not be covered by the same law other than that they fall outside of the jurisdiction of the commissioner? If not, then no.

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

All people are different I can't imagine that there would be a law that could effectively measure everyone with a single 'rule'. Case in point doctors were concerned about a patient I know who had a head injury who seemed to be particularly bad because he would go off on tangents mid-sentence. This was not a result of the head injury - he was always like that, which the doctors were relieved to hear.

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 would like to see delayed consent sought from family, whanau etc as soon as possible after enrollment in the study so that the person can be removed if the family believe that is the patient's wish if the patient themselves are likely to be able to provide delayed consent for some time. The patient should also be asked for delayed consent as soon as they can reasonably provide 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.

The legal requirement that a researcher must show research of a similar nature cannot be carried out on competent persons must take into account that outcomes may be different for different subgroups of the population so that 'competent persons' can not be materially different from 'incompetent persons'. In reality how you establish this may be very complicated.

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.

As long as the intention is to help outcomes in people who have the same or similar condition to the patient being studied.

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 can't think of a good reason why there wouldn't be oversight of studies enrolling people without consent so we know that alternative study designs have been considered first.

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 it is not in the patients "best interests" to participate in the study, if prior consent from family etc is obtained then it is OK to proceed. When treatment must be applied before consent can be obtained then if researchers believe the one of the treatment options is genuinely better, this would not be a candidate for study without consent.

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
- [ ] 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.

Where informed consent can't be given by a patient family/whanau or epoa should be consulted for consent based on their understanding of the patients wishes as early as possible in the processed, ideally before the patient is enrolled int he study. Where possible the patient themselves should be given the opportunity for retrospective consent as soon as they are able to provide it.

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 guard
2 Family/whānau
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 15 March 2017 at 5:38pm | Completed on 22 April 2017 at 6:52pm

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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

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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.

No impact on patient - other than additional blood samples. Will likely help future 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.

Comparing two standard therapies - one of which may turn out to be better than the other.

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

Delayed consent seems to be a valid process.

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.

With the proviso that if the research appears to be causing distress to a particular participant that they be withdrawn from the study.

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 sort of scenario would be very dependent on the type of drug being administered as some are significantly more high risk than others. Adrenaline has well known and characterised negative side effects, whereas other drugs may have fewer side effects.

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

Not sure I understand the 'opt out' process as it is not clear which population group the researcher is recruiting from - any member of the general public or only a specific subset e.g. an identified high-risk group. If the former then the opt out process would not be tenable, if the latter - possibly it would work.

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 is not clear from the statement above how much the benefits of the drug outweighed the risks (in people without Down 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.

Usually family etc have the participants bests interests 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 - because participants who are unable to provide consent have just as much right to best practice which can only be determined through clinical trials.

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

Must be in the patient's best interests (for those receiving the intervention), or without negative effect (for those receiving the placebo).

Proxy consent by family etc and consent to continue by participant when conscious are valid.

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

Many people pull a face when they are having a needle stuck in their arm for a blood sample. Might be hard to interpret facial expressions of say Down Syndrome participants.

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.

This gives the participant the right to chose not to continue to be part of the study.
However, what happens if the participant never becomes conscious again or dies? Does the information collected to date have to be destroyed?

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 what the requirements for being able to prove this would be.

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.

So long as it causes no harm to the participant. Many people, if given the opportunity, would normally consent for altruistic reasons - so no reason to suspect it would be any different for those unable to give consent simply because they are unconscious etc.

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 four points mention
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 already the case - at least no academic research can be carried out without ethical 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?

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 not sure what the current roles 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.***

- ☐ 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
- [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.

- [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 primary clinical researc
2 primary treating clinicia
3 family/whanau
4
5

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

The clinicians (research and/or treating) are probably in the best position to know whether the study is in the participants best interests. Family/whanau will likely rely on their judgement to make their decision.

Final comments

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

Critically ill patients are the sickest in the hospital - their lives are literally on the line - therefore they deserve the best possible treatment options available - which can only come through well designed and executed clinical studies.

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 11:21pm | Completed on 23 April 2017 at 8:29am

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 say this because the treatment to me as the patient will not be amended; I would receive the exact same treatment as if I wasn't a participant in the research.

I would only be concerned by the exact number of tests that measures the changes in antibiotic concentrations.

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 am unsure because I am uncomfortable with being randomly selected to receive one of the two products simply because there is no current research comparing the two products. I am erring on the side of caution because with the lack of research, it is most likely that one of the products is better than the other.

What would push me towards 'YES' is the fact that Dr B will be seeking delayed consent for me. Therefore I recognize here that my rights as a consumer are upheld by the Dr. I am given the opportunity to consent or refuse consent and if I refuse then all data related to me will be removed from the study. This is comforting for me.

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

Delayed consent works so long as this is sought as soon as capacity is regained.

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.

Conventional care and interactive care don't appear to me to result in harm that could be severely detrimental to the patients. The Dr's intention is to decipher which type of care will eventually improve the care of patients with dementia.
The length of the research appears to me to be a deterrent but if it means, i am engaging with the same staff members for that time, then it will assist me as a dementia patient with building rapport.
I feel like this research if it does not provide a benefit to me, it will definitely be of benefit to other patients with 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.

The simple fact that this could cause brain damage is a deterrent. It's worrying because participating in this process could lead to some unintended but anticipated long-term damage.

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

It is important that patients who could not give informed consent are given the option to opt-out of any research. This is a recognition of the patients rights as consumers.

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 known and unknown side-effects make me feel uncomfortable about subjecting those with down-syndrome to take the drug.
The temporary effect of drug is a waste of time.

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 long as it is people that have known and have the trust of the participant.

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.
This is because everyone has a right to not be subjected to medical examination or experimentation. I fear that research may cross the line and enter the realm of medical examination or experimentation which is forbidden.
It is vital that people are all treated with deference and subjecting some and not others to research without their informed consent is disrespectful.

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.

Yes to ensure visibility, transparency and consistency.

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 important because the patient has the right to refuse to participate in the research. Thus if it seems reasonable that the patient is refusing through some sort of action, then it should be respected. I believe a patient will fight with all the means available to them to resist something they do not want. It is therefore crucial that these signs or expressions are treated as final.

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.

This will depend on the circumstance and the belief of the patient. It is so crucial that decisions only made to proceed if there is reasonable belief the patient will give delayed consent. if there is a doubt that the research may be against the person's personal, religious or cultural belief, that doubt should be sufficient to discontinue procedure.

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 don't really have an opinion on this matter.

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 find this barbaric because it undermines the value of the life of the participant. To be quite frank, this is a selfish approach because it is thinking about others as opposed to the participant. I think the research should be conducted without informed consent only if the research is believed to be of benefit to the 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.

Yes otherwise researchers may abuse this opportunity.

Ethics committee must also be comprised of objective professionals that are objective, believe in the research and can recognize that the particpant(s) will be respected

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.

Those making decisions for the participants who cannot give informed consent must be people that have known the participant for a very long time and must have the trust of the participant. They must themselves genuinely believe that the research will be of benefit to the participant without having regard to anyone else. They must value the life of the participant as if it was their own life.

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.

I'm assuming by selecting these that the EPOA and welfare guardian have the absolute of the participant, have known the patient for a significant period of time and value the life of the participant.

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.

- [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.

Similar criteria as EPOA and welfare guardian.

In the Samoan culture, family input is crucial because they know the participant the best. Therefore it is important that family members are consulted about procedures for the participant's benefit. They must be adequate informed and in advance and must not be pressured into reaching a certain decision.

In other cultures, welfare guardians and EPOA play a role so their input must be recognised.

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.

This will depend on who the participant's closest networks/relatives are.

In all cases, where the participant or their decision makers are not familiar with clinical antithesis, it is essential that an objective interpreter or someone within the clinical profession that is completely objective is made available. This person must be able to explain everything to the decision makers in a language appropriate to their understanding in order for them to make decisions.

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 provider
4 researcher
5

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

1 and 2 depends on the patient's closest network/relatives

Final comments

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

The participant has a right to life and a right to be free from medical experimentation. It is so crucial that each participant is treated with respect. Therefore when decisions are made whether to conduct research on them or not without their informed consent, the value of their life must be recognized as upheld. The right people must be consulted and these people must be the closest people to the participant.

I believe it is unfair to conduct research of a participant that may not be in their best interest but may provide valuable information for the benefit of others. This undermines the right of this participant live freely in society and to be recognised as an important member of society.
I can see why benefiting others may be crucial but I believe education needs to be made available about this. People of all cultures must be informed about this in order for them to be familiar with this consent. It's no point giving them no choice, when it is their life that could potentially be put at risk for the benefit of others.

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 April 2017 at 11:19am | Completed on 23 April 2017 at 12:54pm

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 negligible additional risk (only from additional blood tests), and this study could provide valuable information about treating ICU patients with sepsis in the future. The study findings have the potential to save lives and/or shorten the duration of illness.

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 both products are routinely in use, whether they are used on a patient would be 'random' anyway, so it is difficult to see an increase in risk. In particular, I think it is important to include the higher risk groups because they may be more likely to benefit than those who have a less severe condition.

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

Delayed consent is important because it ensures the patient is informed that they have been involved in a trial. While it is true, you can't go back and not administer the trial treatment, it does give patients the option to refuse follow-up and having information collected about them used for the purpose of the trial.
In this trial, the patients would also be consenting to be followed up (for long-term outcomes, complications, quality of life etc).

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 there was a process for identifying negative effects of the intervention, and a plan if patients find it too distressing. Many of these patients would never be able to consent, but they are entitled to be involved in a study which may improve their quality of life and for patients with dementia in the future.

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 reasons given for performing the trial are sound, and previous studies have indicated that the current practice may be harmful. It may improve the treatment of the participants, as well as future patients who have a cardiac arrest.

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

I think it depends on the study, but in this case, I think it is reasonable. The only people who would opt out would be those who were strongly against the research, and were educated enough to know about the study, and follow the steps to get a bracelet. Because of this, I think it is important to also inform patients afterwards that they have been involved in 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.

I'm not sure because the drug had shown serious side effects (suicidal thoughts) and because the drug is not available at the conclusion of the trial.
I would, however, not want my opinion about this study to influence other studies for adults with Down syndrome. I think this group is entitled to participate in research but the risks always need to be balanced with the benefits.

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 most family would be in a position to assess what is OK for adults with Down Syndrome (who are not able to consent for themselves), as I imagine they would have been intimately involved in their care most of their lives, and are likely to be their best advocates.

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 imperative that research is conducted in patients who are not able to consent, so that treatment for these groups can improve. These groups (eg ED, ICU, brain injured, mentally impaired) are the people who may benefit most from improved care and treatment.

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 that the risks to the individual patient need to be balanced with the benefit to society and future patients, as well as to the individual patient.
Researchers need to prove that their studies are safe, scientifically credible and are able to produce a result. They also need to outline safeguards for the patient (ie adequate training, plan if something goes wrong etc).

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

Generally I would say yes, but in some of the scenarios given, it would be difficult to assess if this was related to the study, or their overall discomfort.
In the context of ICU, where my practice has largely been based I would say that what is stated above ('any expression of dissent') is not a very reliable measure of patients refusing consent.

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 participant needs the opportunity to withdraw their consent to being part of a study. Delayed consent gives patients the option to refuse follow-up and having information collected about them used for the purpose of the trial. The process of enrolling patients in studies, then seeking their consent afterwards, need to be recognised in law.

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.

As long as this is not made so difficult that researchers cannot fulfil this requirement. (ie. they should be able to give an explanation about why it can't be done in competent people).

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.

As long as the risk to the individual participant is balanced with the 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.

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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.

Because the ethics committee is independent of the researcher, they are able to protect the interests of the participant, and ensure safeguards are 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.

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
- [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.

Family

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 EPOA or welfare guardi
3 Provide not involved in r
4 Researcher
5

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

The researcher only as part of a team, and where appropriate (as approved by the Ethics Committee)

Final comments

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

Conducting research in patients who are unable to consent is very important for advancing therapies for these groups, and improving their outcomes and quality of life. I also believe they are entitled to participate in research.

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 April 2017 at 11:08am | Completed on 24 April 2017 at 12:27pm

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 does not alter the treatment to the patient.
Delayed consent can be obtained to include the patient's data in the research dataset if he/she regains competency to consent, or not.
The assumption that the patient will not benefit from the research is flawed - the patient may experience sepsis again and may well benefit from this research at a later stage in their life.

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 study the current practice is to use one of two products with no known advantages or disadvantages between the two products.
I assume the patient does not currently get to choose which of the two products is used in his/her surgical procedure. I further presume, the decision about which product to use is currently determined by the preferences of the surgeon, availability and/or cost.

Therefore the only difference I can detect with the research proposal is that the decision about which product A or B to use is driven by a research randomisation tool rather than a preference/availability decision.

All patients will continue to receive care that is in their best interests.

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

I am comfortable with the proposed process for delayed consent.

Assuming the current process does not provide for the patient to contribute to the decision about which product to use in the surgery then the only decision to be made is whether or not the patient's data is included in the research dataset.

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.

First my bias - I have been involved in care in a rest home environment and I think the conventional task focused care practice is questionable.

The proposed research allows for consent from those who are able to consent.

Those who are randomised to the "control" group will not experience any changes in their care but have the potential to benefit from the research in the future.

Some people in the "study" group will not have any negative impact from the research and have the potential to benefit from the research in the future.

Others in the "study" group may have a negative response to the increase in assessments and this should be suitably addressed in the research proposal. For example, something along the lines of delaying assessment to another day if the individual is upset; two attempts at assessment before determining that the individual is negatively impacted by the research and therefore should cease to be researched in the study group.

Findings about people who start out in the study group but cannot complete the additional assessments could be a valuable component of the research 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 there is concern that using adrenaline in cardiac arrests may be harmful to the patient in the long term then I think using adrenaline in cardiac arrests should be considered research already. Just because it is common practice does not mean it isn't research.

I also ask the question - is adrenaline used in every cardiac arrest, or do some clinicians choose not to use adrenaline? If so, then the proposed research may be a process of structuring a current practice in a way that it can better be evaluated.

I would rather we knew with certainty that using adrenaline is safe or not.

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

I am not opposed to the opt-out process but I can imagine it will be very difficult to administer.

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 support this research but only where whanau have been able to give full informed consent.

The benefits for the individual participants may be significant.

The risks can be managed if the whanau know what to look for and are comfortable to manage 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.

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 - I think there will be many examples where the risks of the research are similar or less than the risks associated with not doing the 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.

My greatest concern is about clinical researchers who do not follow the prescribed and/or accepted rules and ethics of conducting human research.

The ethics committee should actively review research practices, during the research period, that involve adult participants who are unable to provide informed consent. It is not enough to give ethics approval or not.

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 purpose of the law is to protect individuals wellbeing. This should apply regardless of who is conducting 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

Every case would need to be considered on its own merits.
Who will determine that a specific facial expression is dissent, or fear, or pain?

If the person is able to understand sufficiently to express dissent about a specific research activity then he/she is able to consent or not.

We already undertake diagnostic and therapeutic clinical procedures on individuals who are not able to make an informed choice about whether they want that procedure or not.

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 is especially valuable where the research did not effect the treatment and the delayed consent is to use data for research purposes.

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 this is common sense. If the research can be undertaken with people able to make informed consent then it should be so.

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, already benefit from research that has been conducted on people that have gone before us.

The participant may not benefit but they may also not suffer any harm from the 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.

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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.

Absolutely imperative to ensure that research is conducted in a manner that meets best practice standards and risks to participants are minimised.

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?

Assessment of the likelihood of harm to the participant.

7.3 Please state the reasons you formed this view.

I am comfortable with the notion that participants may not benefit themselves but may be contributing to future benefits for other consumers.

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.

Any research that involves adult participants who are unable to give informed consent must have ethics committee approval first.

Where time & circumstances permit, consent should be sought from whanau or guardians.

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.

- [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.

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/Welfare Guardian
2 Whanau
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)

N/A

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.

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 12:55pm | Completed on 24 April 2017 at 1:24pm

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.

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	
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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?

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.***

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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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- ☐ 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.***

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- ☐ Consulted by decision-maker
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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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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 9:32am | Completed on 24 April 2017 at 1:49pm

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

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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.

We are answering all of these questions as an Ethics Committee. Yes, as an Ethics committee we would approve this study. We consider this to be a study with no foreseeable harm and which addresses an important research question. The intervention carries minimal risk and the potential benefits are significant.

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 a comparative effectiveness study of two commonly used products, either of which might already be used on patients in a clinical setting. . The committee would allow this study to go ahead but would want reassurance that there is a need to use non consenting participants in the study in order to answer the research question.

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

Clearly in many circumstances this is a nonsense. Patients cannot retrospectively consent to something that has already happened. The question is whether the patients' information and results obtained without consent should be used. As an ethics committee we would therefore insist that on regaining capacity the patient's consent to continue participation should be obtained if the study is ongoing and consent should be sought to use the data obtained.

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 are receiving standard care and the study has potential to improve care in the future. It also has the potential to benefit the trial participants because of increased interaction. The Ethics committee would want the researchers to be more specific about their processes for removing patients from the trial if they show signs of distress. If consent is not possible it would still be appropriate to gain 'assent'.

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.

As an Ethics committee we would like to further clarification about the study and further justification. The study, as described, contains insufficient information for the committee to approve the study. For example the committee would want to see the scientific evidence that the proposal is based on, particularly as it involves a placebo arm rather than a comparison with an alternate agent. There are also major concerns around the definition of 'cardiac arrest' that have not been addressed and it is not clear exactly when adrenalin or placebo may be administered in the context of the arrest. In our view the study as described is seriously flawed and would not be accepted by the Ethics committee.

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

The committee is of the view that this is not a viable option. It is unlikely to work. The actual population that would need to be informed and consented to potentially take part would be huge (many thousands or more) in order get sufficient participants who may end up in a cardiac arrest situation
Also is it safe to assume that someone who is not wearing the bracelet has actually opted in?
There is also potential for this to be a 'waiver of consent' 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 assessments are onerous and intrusive. There is no continued access to the product if the trial proves beneficial. The drug's safety profile is uncertain and the known risks seem to outweigh the potential benefits. There is nothing to suggest this study is a priority for people with 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.

Leaving aside the concerns about the study in general the Ethics committee is of the view that consultation with family would be provide sufficient protection because they are likely to have the best interest of the participant at heart. Where possible assent from participants should be sought and their dissent respected.

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. All clinical care should be evidence based and if treatments are not tested on the target population their treatment cannot progress. This group of consumers is disadvantaged. By protecting these consumers we are harming them by excluding them from the benefits of research. They would either not be given treatments that could help them or they might be given treatments that were not tested on their population and might therefore harm them. All research requires a balance between the interests of current and future patients and a balance of potential benefits and potential 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.

A research ethics committee would need to satisfy itself that there has been good peer review, that the research question is relevant and important, that the research question cannot be answered by enrolling consenting participants, that the participants suffer from the condition that the research is investigating, that family believe that the participant would have consented if they had been able to, that potential benefits outweigh risks and that there is no objection from 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.

There is no reason to discriminate on the basis of the status of the researcher. The issue concerns the rights and interests of the consumer. The right to consent applies to participants, regardless of the status of the researcher.

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

Indications of dissent should always be respected as this shows appropriate respect for an individual's dignity. Enrolling reluctant participants in a trial would also present practical difficulties.

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.

Clearly in many circumstances this is a nonsense. Patients cannot retrospectively consent to something that has already happened. However, their consent to continue participation should be obtained if the study is ongoing and they should have the opportunity to have data collected from them while they were incompetent removed from the study.

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 is an important requirement and the ethics committee need to be satisfied on this point. The gold standard is that research should be carried out on individuals who cannot consent only if the research question is relevant and important, if the research question cannot be answered by enrolling consenting participants, and if the participants suffer from the condition that the research is investigating .

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.

Provided that there is no more than minor increased risk to the participant and minimal discomfort.
The Council for International Organisations of Medical Sciences (CIOMS) in conjunction with the World Health Organisation (WHO) has recently published revised guidelines for research. Guideline 16 relates to research where adults are incapable of giving informed consent. COIMS states that :
1. For research interventions or procedures that have the potential to benefit adults who are incapable of giving informed consent, the risks must be minimized and outweighed by the prospect of potential individual benefit.
2. For research interventions or procedures that have no potential individual benefits for participants, two conditions apply: the necessary data cannot be obtained without participation of persons who are incapable of giving informed consent; and the risks must be minimized and no more than minimal.
3. When the social value of the studies with such research interventions and procedures is compelling, and these studies cannot be conducted in persons who can give informed consent, a research ethics committee may permit a minor increase above minimal risk.
Note that CIOMS has taken a minimal risk threshold approach, rather than a 'best interests' approach.
The CIOMS position is more liberal that the NZ status quo in that it allows a research ethics committee to approve research that present a "minor increase above minimal risk" to adults incapable of providing informed consent, where there is no potential for individual benefit to the research subject, on the grounds of the social value of the research (i.e. benefit to future 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	The same criteria as ab
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 research ethics committee can provide impartial and independent advice and expertise. Their primary role is to protect the interests of the research 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?

The current 'best interest' test is too restrictive and inhibits the development of high quality evidence based care. A risk based threshold would better protect the rights of participants. If true clinical equipoise exists in the research trial then there is no increased risk to 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 EPOA
2 Family
3 Provider
4
5

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

We believe that EPOA's and WG'S should have the right to consent on behalf if all the other criteria in Q5 have been satisfied. Family should be consulted as to whether or not the incompetent person should be enrolled in the study and should be able to provide consent – again if all the other criteria have been satisfied.

Final comments

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

Please state your name

Otago University Human Ethics Committee (Health)

Organisation (if applicable)

Otago University

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 April 2017 at 1:23pm | Completed on 24 April 2017 at 3:31pm

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.

This is not considered as meeting the ethical duties to do good/do no harm because if the research showed the dialysis was clearing the antibiotics more quickly there is no plan to change treatment and respond with more antibiotic if there is a need indicated. Recognised need should be responded to by a researcher. It is not ok to say that this will undermine my research. The research design needs to meet any needs identified. This could then become part of the research.

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.

Dr B has not given information about why there is a need to use participants who cannot give consent. This is not acceptable. Respect for the right to informed consent, transparency and autonomy for health consumers is needed.

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

Delayed consent is not felt to be acceptable because it creates a precedent (potential legal precedent) for this as a practice. It can be considered to be an euphemism for doing what you want and asking permission afterwards, therefore pushing the boundaries and with potential manipulation of health consumers.

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.

Some will be able to give informed consent with the right support. Some may want to be in the interractive group and there may be a need to adapt the research. In our view researchers have an ethical responsibility to provide responses to participant requests, including about best care options available. Also if there is no chance to continue a programme then this is getting the hopes up of those involved and then disappointing them, and the ethics of this is questionable. An advanced directive could be used for informed consent.

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 know that adrenaline has saved lives and is used additionally for allergic responses despite some risk. We would want access to the adrenaline treatment as this potentially could save your life.

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

The opt out process is not seen as sound. This can not be compared to other opt out situations such as used for the NCSP. Bracelets don't always work, even medic alert bracelets can be overlooked.

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.

We query the ethics of this whole research context. The goal of a happy life does not have to be about trying to increase intelligence medically. This is a deficit approach to Down syndrome. Who is made to feel better??? If we consider the ethical principle of the duty to do good and no harm then there are concerns. There are potential risks such as increasing suicidal feelings. There is also the issue that if the drug had positive outcomes there is no provision for it after the research is completed.

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 discussion 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 with strict conditions.

If there is an advanced directive or a truly neutral no harm scenario and potential good for the participant.

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. An advanced directive, which clearly indicates consent and the parameters of consent.
2. A truly neutral scenario - no additional interventions but using existing medical tests results and intervening if a health need is indicated by the research findings at the time. Such intervention can still inform 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.

The best interests of the research participants should be paramount.

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

'No means no'. This can be compared to rape scenarios. A person's autonomy and personal choice must 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.

This can set a legal precedent and is more open to manipulation. Asking permission afterwards for research on vulnerable health and disability consumers is not acceptable.

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 legal standard is not a legal requirement and needs to be. Humanity and personhood for those most vulnerable requires very high ethical awareness and practices.

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 earlier and later discussion about the duty to do no harm and to do 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.

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.

Science has a history of not necessarily being ethical. Very high ethical standards are needed, accountability is needed. Points of comparison to ethical standards need to be made without self-interest. Conflicts of interest needs to be managed carefully.

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?

Yes potentially, if truly neutral, no harm and no additional interventions then this could be a possibility. It also needs to recognise the responsibility to respond to need that might be identified during the research also.

7.3 Please state the reasons you formed this view.

There could then be benefits without risk of 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.

Legal advancement to protect research participants, and develop the requirement to do no harm and to do good as discussed throughout would be supported.

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.

Involve all as per HDC Right 7 (4).
Involvement to indicate it fits with an advanced directive or is truly neutral - no risk of harm, and possible good.

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.

Involvement to indicate it fits with an advanced directive or is truly neutral - no risk of harm, and possible good.

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.

Information needs to be given to show the highest ethical standards - duty to do no harm and duty to do good.

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.

We know that there have been many instances of unethical research and clinical practices in the not too distant past. Women had their lives endangered and some died due to the 'unfortunate experiment', baby girls had 'smears', unconscious anaesthetised participants such as women having a gynae operation (unable to provide or deny consent) have been used to practice IUD insertions unbeknown to them. We know that people in powerful positions can wield power that allows unethical things to occur or to continue, even in the face of some opposition.

The Cartwright Inquiry, the HDC Act and the 'Code of Rights' have been so very important. Research with health and disability consumers needs to be highly ethical and transparent. There should be no manipulation, and there should be strict adherence to the duty to do no harm and a duty to do good which is beyond a superficial level consideration.

Ethical research developments have moved researchers to be more ethical by bringing in a responsibility to consider the welfare of the research participant in more depth when meeting ethical requirements, to see research findings as jointly owned by the researcher and research participants, and to show respect and recognition to research participants for their contribution. This is so very important to the research participant.

Consumer autonomy and protection of vulnerable consumers is vital. We want medicine and science to learn and grow but not through exploitation of others, and especially not through exploitation of vulnerable participants unable to give consent. This is a very difficult area of consultation and on the surface some of the scenarios appear to be reasonable but when delving a bit deeper something that appears to not be harmful does have potential for harm. Where to draw the line is what is being asked here. The line needs to be drawn high so that there is a full duty to do no harm and a duty to do good adhered to in each case. There is also the fear of the slippery slope and setting precedents that erode the rights of health and disability consumers. If there is any risk then this needs to be made fully transparent and full informed consent attained.

Please state your name

Organisation (if applicable)

Palmerston North Women's Health Collective

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 25 April 2017 at 6:26am | Completed on 25 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.

I can see no harms to me as a participant in this research. In ICU I will have an arterial line from which blood tests are routinely drawn so there would be no extra needles/pain. Also, if I recover I might have another serious infection in the future so it is possible that I may benefit directly from this research. On a similar note, others may also benefit from this research which would be a good thing.

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.

At the moment I would be given one of these products at the whim of the treating doctor. Although most doctors think they are recommending products in the patient's interest, they may be unduly influenced by the manufacturers of such products either consciously or subconsciously. I would rather that I and other people were given products that were proven in well designed studies to be better or (if equally as good) cheaper than other products and therefore would like to be part of research that helped to provide a higher quality of evidence about treatments than one doctor's opinion.

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

I believe that delayed consent is a good idea, as it would allow me to decide whether my information was used in research if I became competent to do so. The only issue would be if that I if I did not survive the surgery or was permanently incapacitated by it or the underlying condition I would not be able to provide delayed consent. However my view is that if an ethics committee has agreed that the research is worth doing on the basis that there is true equipoise then I would happily be enrolled in the study without my consent as I would be contributing to the greater good for society and my death or incapacity would not be wasted.

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 it is important that people with impaired capacity do not miss out on treatments which are based on high quality evidence. By being part of this research I may help others to have an improved quality of life during the final stages of what is a terminal illness (dementia), which I believe would be a good thing. This would also mean that despite my incapacity I would still be making a contribution to society and be helping others through improved knowledge about how best to help people with dementia have a better quality of life.

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 body of evidence is such that there is equipoise now so a high quality study is required.

Although adrenaline has been shown to improve survival to hospital it has not been shown to improve neurologically intact survival to hospital discharge and it may actually be harmful. If adrenaline was removed from cardiac arrest algorithms these would be easier for providers to learn and follow, which may mean that time and energy is not wasted on useless or harmful treatments during the cardiac arrest (eg putting in IV lines, drawing up drugs instead of doing good quality CPR, defibrillation and transporting to definitive care).

Although I may not benefit directly from this research, especially if I died as a result of the arrest, others like me would benefit and this is a good thing. However if I survived my cardiac arrest and had a subsequent cardiac arrest I also may benefit directly from this research.

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

My initial reaction is that I do not like the idea of the 'opt out' process.

A public awareness campaign would be costly and unlikely to have much uptake (example is medic alert bracelets which very few people wear even when they have significant medical problems or allergies). Furthermore, such a campaign would be unlikely to reach all people who would wish to 'opt out' and therefore absence of a bracelet would provide no guarantee that a person would have wanted to be in the research. Very few people have cardiac arrest so the campaign would be irrelevant for the vast majority of people who saw it. Unless worded very carefully it may risk alienating people against any medical research.

On the other hand it could be argued that an 'opt out' campaign like this may stimulate discussion about medical research in emergency situations in the community which may which may allow for more informed discussions. It also gives those who have definite views against researchers improving the way we care for people a chance to express these views.

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 scenario gives no indication of the theoretical basis for why this drug may be beneficial, and suggests that there may be harms (increased suicidal thoughts). As the drug would not be made available after the trial was competed there is no potential for long term benefit for the participants.

My concern is that 'Dr E' is acting for a pharmaceutical company (either consciously or subconsciously) and that this is not true investigator initiated research.

This principle applies especially in the NZ situation to new drugs from overseas which PHARMAC are unlikely to register due to cost. I do not believe that New Zealand or New Zealanders should be a testing ground for experimental therapies / novel agents that will not be made immediately available to New Zealanders at the conclusion of studies at an affordable price.

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 one assumes that they are acting in the best interests of the person then this may be sufficient protection for that person, if the friend or whanau / caregiver is competent to make that decision and there is true equipoise between proposed treatments in an intervention study or the study is minimal risk observational research. However, in the above scenario there is concern that the drug is harmful from the phase 1 or 2 studies and no evidence provided that it may be beneficial. I am not confident that a surrogate decision maker should be able to give consent in this setting.

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 does not make sense that clinicians are allowed to give unproven or potentially harmful or expensive treatments based on our individual opinions (which happens hundreds of times every day in NZ), but we are not allowed to conduct studies which would demonstrate whether treatments are more beneficial or safer.

Observational research which does not involve more than minimal harm should be allowed.

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 condition / persons for whom the research is proposed is such that informed consent is not possible to be obtained.

The study should be for the public good and not the benefit of a commercial entity (private company).

The study is observational research where there is equipoise between treatments (for example where two treatments are currently considered 'standard of care' but insufficient research has been done to determine whether they are different or not).

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 does not make sense to have one rule for one group and another rule for another group. From a research participant's perspective what is the difference who the researcher works for?

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 sounds reasonable as it is the closest we can come to finding out what the impaired individual actually thinks. Some people just don't like the thought of being in a study and this is their right. However trying to interpret the facial expressions as described above will be very subjective. Impaired persons may demonstrate those expressions simply by being out of their usual environment, or in the presence of strangers, due to the acute condition they are suffering, or by associating a medical setting with painful things like blood tests. So how would we know that it is the research they are apparently objecting to?

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.

This has already happened in several studies conducted in New Zealand, with very low rates of subsequent denial of consent to use information. So the current law is been ignored by both ethics committees and researchers if the interpretation of the law provided above is correct.

People with the most serious illnesses should not denied the opportunity to contribute to knowledge. Denying them to opportunity to participate also introduces a selection bias into studies (towards those who are less unwell).
This way the quality of research and the generalisabilty of the research results to the sickest or most injured will be improved.

Allowing people to retrospectively consent will respect their autonomy in regards to being a participant in research. However this should only apply to public good interventional research (not for the benefit of commercial entities) where there is equipoise between proposed treatments.

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 would be difficult to apply as a blanket rule. It may be valid for some intervention studies but for other intervention studies it may be that potential benefits or harms may only be evident in those with more severe illness or injury, or those who are otherwise unable to consent, so research on those who are able to consent may not be relevant or transferable. When there is minimal risk to participants (eg observational research) then there should be no such requirement. The practicality of such a requirement is unclear.

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 situation for all research into resuscitation for severe illness and injury. Currently we can treat such people with treatments that have not been proven to be safe or effective, yet we are not able to conduct research to determine what the best and safest treatments are. This makes no sense.

My personal view is that I would like to contribute to the greater good in the situation where I was about to die so that my death had some value to society.

Similarly if my health information was to be used for the purposes of public good (not for profit) research without my consent I would be happy with that as long as I was not personally identifiable in the research results.

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 people being studi
2	The research should be
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 must admit that I thought this was already the case. It is very important that we build in protections for vulnerable people when it comes to research participation. Ethics committees are the logical group to provide that protection

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?

There should be a threshold test such that by participating in the research the person is at no greater risk of harm or benefit than if they didn't participate (ie - there is equipoise between the treatments).

7.3 Please state the reasons you formed this view.

It is illogical to allow doctors to give people unproven treatments but prevent them from doing studies to find out which treatments are best.

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

Decision-makers.

EPOA

Additional comment.

Veto retrospectively or provide consent or not, only if the family/whanau are aware of the views of the incompetent person towards being a research participant (ie can reflect the person's views, rather than their own).

Sometimes in emergency situations, involving whanau/friend or family in a fully informed consent process will be too time consuming and render the research invalid eg when treatments need to be given immediately or within an hour - it takes time for proper consultation with whanau, especially when the whanau who are present want to discuss with extended family who may not be present and this process can take many hours.

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.

If the family/whanau are aware of the views of the incompetent person towards being a research participant (ie can reflect the person's views, rather than their own).

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?
- [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.

EPOA

Additional comment.

The provider should be an objective assessor of the research and whether there is undue risk to the participant. They will add a layer of protection for the participant with respect to research participation.

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.

Veto retrospectively only if the provider is aware of the views of the incompetent person towards being a research participant (ie can reflect the person's views, rather than their own) or becomes aware of harm to the participant due to being in 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.

Researcher who is conducting public good research (ie not for the benefit of a company who will profit from the research).

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.)
- [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.

EPOA, Whanau, Clinician caring for the patient

Additional comment.

Sometimes in emergency situations, involving EPOA or whanau/friend or family in a fully informed consent process will be too time consuming and render the research useless eg when treatments need to be given immediately or within an hour - it takes time for proper consultation with whanau, especially when the whanau who are present want to discuss with extended family who may not be present and this process can take many hours.

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
- [x] Provide or withhold consent on behalf of the consumer
- [ ] Other

Additional comment.

Observational studies which are minimum risk to participants (as specified under current HDEC guidelines) which have been approved by an authorised ethics committee should also be able to be conducted without the need for individual informed consent if this is in the patients best interest or for the benefit of other patients like them.

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/Whanau
3 Responsible Clinician
4 Ethics Committee
5 Researcher

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

Sometimes in emergency situations, involving EPOA or whanau/friend or family in a fully informed consent process will be too time consuming and render the research useless. For example when treatments need to be given immediately or within an or two hour - it takes time for proper consultation with whanau, especially when the whanau who are present want to discuss with extended family who may not be present and this process can take many hours.

Ethics committees should be able to make decisions about consent being waived and have a deferred consent process in certain situations for interventional studies - where the participants are incompetent AND immediate enrolment required for the treatments to be effective AND equipoise exists between the treatments AND the research in the public good (not for the benefit of pharmaceutical or device companies). See further comments on the next page for a suggestion about a multi-stage consent process in emergency situations.

It is very important that researchers who have a commercial interest in the product being studied or close personal / professional or financial ties to the company / representatives of the company that makes the product do not have sole discretion to enrol a vulnerable person into an intervention study.

Final comments

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

1. Has the commissioner considered that under current law research in emergency conditions that people may suffer from more than once may will be in a potential participants best interest?
For example it is not unusual for people to have more than one severe injury or infection in their life (especially certain high risk groups) and people with chronic conditions that have recurrent acute exacerbations such as chronic obstructive respiratory disease, asthma, ischemic heart disease, heart failure and so forth. In these settings the standard of being in that person's best interest may be considered to have been met.

2. In emergency situations there may be scope for a staged consent process, where by a potential participant may be sufficiently competent to indicate after a brief discussion with the researcher and treating clinician that they would wish or not wish to participate in a research study that requires urgent enrolment with the opportunity for them to subsequently withdraw consent at any stage.

The brief discussion would need to include why the study was being done, that participation or not would not change other treatments/care and what the major risks involved were. This may include brief written information in simple language. However this would not mandate full written informed consent at the point of study entry. It is unlikely that an acutely unwell or injured patient is capable of going through a 5-page small print consent form comprehending all the issues even if they are usually competent.

This would mean that people who are against any sort of research participation or the general concepts of the particular study in question could express this to the researcher and they would not be enrolled. Those who were not adverse to research in principle would have the opportunity to discuss this with the researcher / treating clinician and to participate if they wish. They could still withdraw at any time.

Once their condition has stabilised they would then have the opportunity to consider the full study details and make a fully informed decision in retrospect and again have the opportunity to withdraw their consent.

In this way the principles of autonomy are respected along with the principle of natural justice (being given the opportunity to participate).

Observational studies that pose minimal risk to participants should not require consent as per the current HDEC guidelines.

Please state your name

Organisation (if applicable)

consultation period has ended. All submissions that you make on this consultation are 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 26 April 2017 at 10:07am | Completed on 26 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.

Because apart from extra blood and urine tests there would be no disadvantage to the patient but this could be imperative for future patients of which they have the possibility of being 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.

Because both products have been clinically approved and are currently being used. This will not affect the patient.

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

I think that is reasonable and should be required if 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.

Because the conventional care is far from satisfactory

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.

Having worked in Coronary Care and seen 1st hand the benefit of using adrenaline and the effect of not, I would definitely want it to be used. I appreciate the difficulty in assessing the long term outcome but feel this study would put patients lives at risk.

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

Not reliable enough. Few would bother possibly. Huge undertaking and people believe they're immortal and it will never happen 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.

Because of the interference in the lives of the disabled person. The 6hr assessments which they may not be able to understand and the possible side effects of the drug. Seems like very few if any advantages for the person with Down.

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 the family may be willing they may not totally appreciate the effect on the disabled person and the fact it would possibly offer them any benefit.

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 it clearly can be of advantage to the participant and if it doesn't put them at risk at all or impose painful procedures.

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 it is most likely to be of benefit to the person involved.
If it can be assured that there would be no risk or pain to the person 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 situation is the same regardless of 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

There is little real understanding of what the participants are able to comprehend and all attempts at communication must be taken seriously.

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.

Depends on the research and the effect that is likely to have on the participant. If as in the case of neurosurgery it will not effect the treatment then this could be allowed with the opportunity for the participant/next of kin/guardian to withdraw if requested.

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.

Why use people who can't consent if it can be trialled on those who can?

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.

Appreciate need to be able to study particular conditions and believe this should be done on people who are able to give consent in the first instance.

If unable to consent the risk, pain, time factor and interference in the lives of these people must be seriously considered by all those involved in the consent process

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 further safeguard for those unable to 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?

The risk/benefit analysis
The pain, time and inconvenience the participant may endure

7.3 Please state the reasons you formed this view.

As the Welfare Guardian for my disabled daughter I know she would not cope with some of the tests that maybe involved and I believe other adults who are not able to consent may well be in a similar situation.

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.

All people conducting Health and Disability research on those unable to consent should follow the same laws.

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.

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.)
- [ ] 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
- [x] Other

Additional comment.

Possibly to provide additional information

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 Guard
2 Family/Whanau
3 Provider not involved in
4 Other who provide infor
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.

My answers are from the perspective of my role as Welfare Guardian for my disabled daughter but also from my nursing background. I have also been involved in disability research which has required Ethics committee approval

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 27 April 2017 at 2:52pm | Completed on 27 April 2017 at 3:57pm

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.

While this study may not help me personally, it is not going to harm me and may of benefit to 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.

From the scenario, both products are approved and the neurosurgical team could use either product without asking for my consent. I see no problem with them randomising me to either product. There is the potential for benefit to others if one of the products is shown to be superior to the other.

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

Appropriate. I'd want to know that I'd been enrolled in a study if my capacity improved.

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 devastating illness that I would be willing (now while I have the capacity to say so) to take part in such a research study. There is a potential for benefit to me (or harm) and the potential to benefit others in the future.

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.

From the scenario, there is no good evidence of benefit of adrenaline and it may actually be harmful. There is potential benefit, or harm, or no difference but we don't know at present and I'd like to think something good could come from such a devastating event.

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

Seems unworkable. Is she suggesting every NZ'er (or even cardiac patient) wears a bracelet like 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.

If the drug did lead to an improvement then it seems unreasonable for the developers of the study drug not to supply it to those who participated.

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.

People with Down syndrome should have the same right to take part in research as anyone else. If the drug was effective and were made available after the study then I would think it appropriate to enrol them if their family/whanau agreed - they know the person best.

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 - when there is potential to benefit them (e.g. new treatment with early promise versus standard care) or if the interventions involve treatments that are in use but without good evidence and there is a genuine concern about this. Also, when an intervention or investigation is going to have a trivial effect on a person (e.g. additional blood tests or the recording of clinical 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.

There must be a solid rationale for the study.

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'd be concerned about forcing a one size fits all law. There are differences between those who can and can't provide informed 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

The competence to consent is not and all or nothing thing. For example people with Down syndrome who may not be able to provide full informed consent are more than capable of expressing 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.

I believe it is appropriate in some life threatening situations to enrol people into research studies. If a person regains the ability to consent of course that should be sought. How can this not be allowed? For example, what happens if the study requires ongoing interventions or assessments?

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.

Vulnerable people should have the right to take part in research (with appropriate ethics committee review) just like anyone else.

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.

As long as there is a solid rationale for the study and it has gone through careful ethics committee review.

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	People with same cond
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 had thought this the case now.

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 the potential for benefit (new intervention/therapy vs standard care) with a clear hypothesis and good rationale. Alternatively, low risk assessments (e.g. blood, urine, results of clinical assessments).

7.3 Please state the reasons you formed this view.

I don't understand the logic of the best interests statement as above. If you thought the consumer would be better off participating in the research than not, then why is the study necessary? Surely this simply prevents a whole group of people from the opportunity to take part research. Isn't this unethical, as long as a study is reviewed and approved by an independent ethics committee?

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.

Unsure as to what is meant by these statements.

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.

I would trust my spouse to make a decision that was in my best interests if I was unable to do so.

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.)
- [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.

Family/whanau

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.

Spouse, family/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.***

- [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.

- [ ] 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 welfare guardi
2 Family/whānau
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 27 April 2017 at 2:13pm | Completed on 27 April 2017 at 4:14pm

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.

No.
Who decides whom is allowed to be used as research participants without their consent? It has the potential to lead to an increase in the statistics (which are already high) of abuse against people with impairments.

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

Ethics Committee approval in all circumstances

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 leaves scope to wide open for 'incompetent' (wording I do not like) adults to be taken advantage of if the law only pertains to research carried out in relation to health and disability issues/service providers. Needs to cover all types of research so our most vulnerable citizens are protected in all situations.

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

United Nations Convention of the Rights of Persons with Disabilities states the following (see below), the law should be in line with this convention.

Article 15
Freedom from torture or cruel, inhuman or degrading
treatment or punishment

Article 16
Freedom from exploitation, violence and abuse

Article 17
Protecting the integrity of the person

Article 21
Freedom of expression and opinion, and access
to information

Article 25
Health

Article 28
Adequate standard of living and social protection

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.

Again, it leads to the issue of potential abuse/harm against people
What if the person disagrees with what has been done to them? What would be the consequences?? It is too late then
Only exception - would be if the procedure is life-saving

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 don't think research should be carried out on 'incompetent' persons at all, in any circumstance

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.

Ethics Committee approval should have to be gained in all circumstances.

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 believe research should be permitted to proceed without the consent of adult 'incompetent' participants.

7.3 Please state the reasons you formed this view.

'Incompetent' adults have the right to the protection from harm as much as any other adult or person does.

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.

Currently "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."

I think the term 'best interest' is far too broad, and open to personal opinion. It does not provide enough protection for 'incompetent' adults.

Decision-makers often end up being medical professionals - using the medical model. I believe that they would not necessary be making decisions in the best interest of the 'incompetent' adult e.g. when a doctor suggests to a family it would be best to about a pregnancy rather than have a child with a disability). The whole picture is not provided, opinions can easily be swayed one way or the other.

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.***

- [ ] 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.)
- ☐ 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 Family
3 Provider not involved in
4 Other
5 Researcher

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

The researcher themselves should never be a decision-maker deciding whether an 'incompetent' adult can be involved in their research. Conflict of interest.

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 25 April 2017 at 3:38pm | Completed on 27 April 2017 at 4:17pm

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.

clinical condition management remains the same
minimal risk of harm from participating (although a blood test is invasive)
can't test on anyone else other than that class of persons
conditional upon science review -
(a) assumes we know how fast antibiotic concentrations move through humans under normal conditions
(b) sepsis response level may be different in different patients or in reaction to different infections
knowledge gained might help others needing dialysis from sepsis
IC to participate/or not must be obtained from next of kin or legally authorised person (including explaining 'a special form of dialysis' & the extra tests required)
If patient is enrolled in the study they must be told about it if/when they regain consciousness & if they wish to withdraw from the study their samples must be destroyed & their individual data removed from the study analysis/findings

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.

patient still gets current treatment for which either product is safely & effectively used
no added risks
presume the decision to treat is the same for all patients based on utility rather than capacity for IC
patients with capacity for IC must be told beforehand (even though the treatment they receive will not be different)

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

DC not relevant in this scenario as patients are already in the research and their treatment would not have differed from normal (neither can the drug received be withdrawn from their body)
BUT
because the treatment drug the patient received is being compared with another treatment drug the patient must be told about this (when capacity is regained), the reasons for having blood & urine tests explained, and given an opportunity to receive the results of the study
If the patient doesn't want to have any more tests they should be given the opportunity to withdraw from the study at that point.

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 study is about persons with severe dementia. What is the reasonable prospect of any benefit to that individual?
If the person had given an advance directive pre-severe dementia onset that they would be willing to participate in dementia studies then they perhaps could be considered for enrolment - subject to suitability of their current condition (not unduly agitated, type of stimulation is acceptable/appropriate to their current state, etc). Next of kin/legally authorised persons should still be informed about the study.
Everyone - including those with dementia - has the right to be in a stimulating environment with 'interactive care' so the potential benefits possibly outweigh any (low level) risks of harm.
If the person displays distress from participation or unwillingness to continue then a lesser degree of stimulation could be considered, or they should be withdrawn from the study.

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 patients either want/expect normal treatment or no treatment (as per advance directive) but randomisation is not appropriate when the outcome could be paralysis or death without intervention.

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

Only OK if there's an explicit 'no treatment' advance directive, but this also depends on the level of damage and time taken to get to assessment - at what point would the advance directive kick in?

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.

learning levels are fairly established by the time of adulthood
different levels of Down syndrome capacity - no selection criteria
can't access the drug afterwards even if a benefit was to be evidenced in some potential participants
risks are too great - if the drug has been shown to induce suicidality in anyone it should be banned

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 are more than minimal

the benefits are purely speculative, especially for adults

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 participant's interests may be advantaged & risks are minimal & can't test on any other competent persons
eg persons with dementia who have given an advance directive willing to be included in dementia studies before onset of incapacity; or persons with rare disorders
- not all persons are necessarily incompetent beyond the research period eg unconscious patients

NO - some will never be able to fully appreciate the risks/benefits, and it is not necessarily safe that other persons with legal authority can give their consent on behalf of the incompetent person - those others will not be the ones injured or harmed should an adverse event arise
- the 'best interests' test is insufficient. I note that competent persons have the option to not participate in research without question or consequence, even if the 'best interests' threshold (for that individual and/or that class of individuals is met) & risks are minimal, yet researchers /research clinicians want incompetent persons to be included in studies for 'the public good of science'. But the full research data may never be publicly available for independent scrutiny (a good science test), the outcome may never be a marketable product, or if it does it may not be affordable - and the research participant has no say in this.

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 observational studies - and never RCTs

there must be a reasonable expectation that the individual potential participant's best interests will be served (not just participation to serve the public good)

the maxim "nothing about us without us" requires that incompetent individuals with particular conditions be included in the studies from which the knowledge that forms the basis of their potential treatment is developed (ie no testing of drugs on competent others & assuming it will work on them/those with their condition), but also rightfully requires IC from those participants. In an ideal state this could be achieved, but the current NZ research environment is far from ideal from a participant perspective.

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.

Too much emphasis is placed on the public good benefits of generalisable knowledge when recruiting research participants, yet the wider research environment and the supporting system protections in NZ are far from robust. Ethics committees have moved from ensuring participants' interests are protected to facilitating research yet they don't get to critique the science behind studies they approve. Not all NZ research participants are covered by ACC should adverse events occur. Not all study data outcomes are necessarily disclosed or openly published, and in today's environment of shared big data, academic studies are creating even greater (and usually undisclosed) future risk for the individual participant.
Incompetent persons are likely to be even more vulnerable in this scenario.
We must have more robust wrap-around systems for all research participants and a more widely informed general public, otherwise we risk allowing other legally authorized persons to give their 'consent' for research participation on behalf of incompetent persons that is inadequately informed but never shoulders any of the risks.

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 - the non-maleficence principle of 'do no harm' must be respected and adhered to

IC should equally be balanced by acceptance of withdrawal of consent and the latter should be accepted when indicated by as broad a range of signals as possible for that individual

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.

can't take drugs out of the human system once they've been introduced

DC makes a mockery of IC that necessarily precedes any agreement to participate in research or not

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.

involvement of the class of incompetent (potential) research participants being recruited must be restricted to research situations that only applies to them, and any expected benefit only applies to them or that class of 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.

some behavioural research may not even go to an H&D ethics committee

if there is no reasonable expectation of benefit to the individual n their lifetime (even as one of a class of which no others can be included in the study) then the research shouldn't proceed at all.

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	minimal forseeable risk
2	minimal forseeable bur
3	IC of legal representativ
4	no indication of dissent
5	EC approval
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.

need to accept that EC review is about limited aspects of the study only, although this is undertaken on behalf of society generally

neither researchers nor ECs should have any weight in de facto enticement to participate in research

need to be internationally consistent - all overseas models require this

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/burden

should always be a minimal risk/burden threshold

must also be a strong expectation of benefit for the individual to be included

7.3 Please state the reasons you formed this view.

the minimal forseeable risk/burden threshold (as in Scotland) usefully specifies an upper limit of risk

researcher bias inevitably favours participation

when a potential participant is one of a special class that excludes competent patients it is easy to slip into 'for the good of that class' of patients mode and the participant is one of them

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.

Any law review should start with those who approve studies in the first place. Ethics Committees must be underpinned by statutory regulations; their scope of review powers must be widened to include the science; and they must be required to ensure that all NZ research participants are treated equally in the event of harm arising from participation in studies.

Currently a researcher consults with 'suitable persons' but even seeking consent from a legal representative is inadequate as that person never experiences the risks / adverse events.

IC by a legal representative is still limited in that participation in research is usually presented as 'doing good' and normative in the first instance.

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.

urgent lifesaving measures are about clinical treatment (b & d)- yes, they would have a say in that, but this would not be research

Additional comment.

EPOAs and welfare guardians should be routinely included in ongoing care plans, but only in a very small number of possible cases could they have a voice in research participation/not - within the current NZ research environment. Influencing factors might be: what the individual had indicated while previously competent; if the current state of 'incompetence' is temporary or not; what is the nature of the potential benefit for that individual & the risk of harm to that individual.

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.

Not in the current NZ research environment. Very risky. Family are more likely to ensure ongoing relations with the clinical caregivers are positive and to be persuaded that participation in research is normative practice. Potential benefits arising are routinely oversold and reality limitations of outcomes are rarely mentioned.

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 family/whanau
3
4
5

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

The EPOA or welfare guardian has a legal duty which can be contested if they fail to consider the individual's best interests. None of the others can be held to be legally and ethically accountable for ensuring the potential research participant's best interests are protected. A researcher, attendant clinician, or clinician/researcher inherently has an automatic bias towards their own trade of practice and are more likely to oversell benefits and understate risks.

The current NZ research environment offers minimal participant protection in the event of harm arising, gives very little acknowledgement of the altruistic participant role in contributing to scientific learning (results may not even be published nor shared with competent participants, yet alone those who might assume powers of consent for involvement of incompetent participants). There is a constant political pressure to persuade citizens that participation in research is not only a duty but also a forerunner of new and better treatments, and even further, that research is an economic earner for NZ. None of this bodes well for obtaining informed consent from another party who never experiences the risk of harm associated with research participation. Incompetent persons are already vulnerable. Loosening the current regulations to allow others to give consent on behalf of the incompetent person only risks increasing their vulnerability.

Final comments

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

As previously stated, the current NZ research environment does not even protect competent research participants' interests adequately now.
Furthermore, we cannot rely on the current ethics committees (ECs) SOPs to ensure all participant's best interests are adequately protected. There must be change to bring ECs within more robust regulatory control before the current scope for recruitment of research participation is widened.

Involvement of incompetent persons (whether this is a temporary or long term state - and to what level of incompetence?) in research at present is unacceptable unless they have given express indication prior to their loss of competence that they are willing to participate in research (such as dementia studies), assuming the risks are minimised and the expected benefits are reasonable. Presenting 'inclusion benefits' of participation in any study (eg improved or more watchful care) should never be presented/weighted as a study benefit.

The law should not be changed at this point in time to allow decision making by others to consent incompetent persons to being enrolled in research within NZ until better protections are in place for all research participants.

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 27 April 2017 at 7:17pm | Completed on 27 April 2017 at 8:01pm

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.

Ethical approval of this research would ensure it is deemed valuable for all consumers, whether they could consent or not. Many people with sepsis could not consent regardless of their previous health. We would want our designated next of kin (or support person) to be informed and to help with the decision to be included

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 per above, it would be appropriate to have the consumers designated next of kin or support person help with decision making at a time when the consumer could not make that decision.

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

It would be imperative that the consumer be informed following if they regain capacity so that they have the opportunity to understand the research, ask for results from the study and to decide against using their data 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.

People with dementia have the right to contribute to research if they would like to. Mental capacity is not black and white, but rather runs along a continuum. Many people with dementia can make informed choices about being part of research if what is

involved is clearly explained, but could not make more complex decisions such as those regarding finance. The consumer with dementia should also designate a next of kin or support person they trust to help them with this decision making.

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.

Ethical approval of this research would ensure it is deemed valuable for all consumers, whether they could consent or not. Many people with sepsis could not consent regardless of their previous health. I would want my designated next of kin (or support person) to be informed and to help with the decision to be included.

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.

It is the same as the answer to C.2, People with intellectual disability have the right to contribute to research if they would like to. Mental capacity is not black and white, but rather runs along a continuum. Many people with intellectual disability can make informed choices about being part of research if what is involved is clearly explained, but could not make more complex decisions such as those regarding finance. The consumer with intellectual disability should also designate a next of kin or support person they trust to help them with this decision making.

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.

Often the consumer may have a conflictual relationship with family members, or family members have conflictual relationships among themselves. The consumer should be asked whom they would designated as their trusted next of kin or support person to help them make decisions. If the consumer is unable to indicate their preference to be included in research or a trusted next of kin or support person at all, then only designated and activated EPOA or welfare guardian should be used to obtain consent.

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.

Exclusion from research of otherwise eligible persons with cognitive impairment for example (or with other health issues that fluctuate) whether or not they lack capacity to consent is discriminatory and violates ethical principle of justice [1]. People with cognitive impairment, for any reason, are entitled to have opportunities to participate in research. Furthermore, such exclusion can further exacerbate already existing vulnerabilities by further marginalising people [2]. Research designs need to seek to maximize opportunities for inclusion of people [3]. This translates as extending opportunities for informed consent based on information provided beyond the written word. For example, using visual information, audio information, use of artefacts and as stated on page 11: The information must be communicated effectively in a form, language and manner that enables the consumer to understand it. This is contradictory to the later statement on page 12: Once the consumer has been informed appropriately, he or she must provide written informed consent excluding people who are unable to write for any reason. Restrictions should apply only if it is clear that the design of the research including the consent process is evaluated by an approved ethics committee as not being appropriate for participants and in relation to the aim of the research.

[1] Alzheimer's Australia 2004, 'Research consent for cognitively impaired adults' recommendations for institutional review boards and investigators, Alzheimer's Disease and Associated Disorders, vol. 18, no. 3

[2] Dewing, J 2007, 'Participatory research: a method for process consent with persons who have dementia', Dementia, vol. 6, no. 1, pp. 11-25

[3] Murphy, K, Jordan, F, Hunter, A, Cooney, A & Casey, D 2014, 'Articulating the strategies for maximizing the inclusion of people with dementia in qualitative research studies', Dementia, vol. 0, pp. 1-26

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 should be aware however that research methodologies are not limited to Quantitative research i.e. the current assumption of the HDC that research methods are either observational or interventional is problematic in and of itself. That is, this assumption does not maximise the needs of people who may have difficulty providing consent potentially going against the very principle stated on page 8 of the consultation document "nothing about us without us" In other words, Informed consent is not a fixed and static event but rather a dynamic and ongoing social process.

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

Even if there is doubt about the reason for dissent or refusal, the researcher needs to assume that a person does not wish to participate and in keeping with ethical and moral principles of avoidance of coercion. As outlined above however, the law should be worded in such a way as not to risk further marginalising vulnerable people by assuming that expression of dissent or refusal is final and definite. That is by viewing informed consent as a one off static event rather than an ongoing process. See for example the method of process consent outlined by Jan Dewing [2].

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 should be possible under the law under specific circumstances deemed appropriate by an ethics committee.

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 is not ethically justifiable to exclude people from the opportunity to participate in research both at the level of the individual and the level of society.

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, the premise that most research with incompetent participants is uncertain and/or does not benefit a particular participant is highly problematic. There is evidence to suggest in our own field of gerontology and palliative care research that people involved in research often receive better care than those who don't as described on page 15: inclusion benefit, which is where a consumer benefits from being enrolled in research because he or she receives better monitoring and care than is received through standard care, or is helped by participating in a qualitative research process, such as an interview. For participants reaching the end of life, this is highly significant. For these people participating in research may result in improved symptom management and end of life care. These experiences can be enduring for family members who have to live on after the death of the person. This may be particularly critical for example, for someone with a potentially reversible delirium for whom being involved in the research improves quality of time and may even extends time for a person, family and whanau to discuss and deal with unfinished business. For someone with advanced dementia cared for in an ARC setting, being involved in research may mean increased interactions and engagement with others. For example, studies researching non-pharmacological interventions for behavioural Psychological Symptoms of Dementia have highlighted that engagement in and of itself appears to be the significant factor in the success of any intervention.

Further, there may be certain circumstances to carry out research with people who are unable to consent on the basis that the research may be part of 'usual practice' and do no harm to the individual but may benefit their family, whanau and/or 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	an ethics committee should
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.

In keeping with the law in other countries and highlighted in the consultation document, this would seem a reasonable approach so that research ethics might be evaluated in context of the research and its application and population rather than on a blanket rule while also providing a safeguard. This would require ongoing monitoring of the make up and standards of human research ethics committees.

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?

As the consultation document highlights (Page 15), the current 'best interests' test: does not provide for any consideration of the potential
for advances in knowledge that may benefit other people. Further it appears to privilege the decision-making of clinicians rather than participants and the public and does not account for inclusion benefit.

In this instance where the benefit is unclear, it would be appropriate for a proxy consent process to be developed if the person does not have the capacity to judge if it would be in their best interest. This should only apply If the person without capacity to consent has legally designated and activated Endursing Power of Attorney (EPOA) for Health and Welfare. The EPOA is legally bound to make decisions for the person unable to consent that are in best interests of the those unable to make informed decisions. It would unethical to ask anyone to participate in research that would be harmful to them whether they have the mental capacity or not to consent.

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 NZ law needs to account for a more socially nuanced concept of informed consent that minimises the risk of a single individual or health care provider/ other professional deciding on behalf of a person and that accounts for cultural context in terms of autonomy and decision-making.

As discussed in question 7.2, the law should accommodate ways for a decision to be made to participate in research by the designated and activated EPOA for the person unable to consent.

'Best interests' should not be decided by one person or one health care provider alone.

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.

Only when the EPOA is legally designated and activated.

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.

when nominated by the incompetent consumer as their substitute decision-maker through an EPOA.

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.

The consumer's responsible clinician (such as a GP, Nurse Practioner or specialist in the area that would have expertise in determining capacity such as mental health, geriatrics or palliative care can indicate that they would not assess the person as having the capacity to make an informed choice. If the person is deemed to lack to the capacity, then there should be a provision for the legally designated EPOA to be able make a decision based on what would be in the best interest of the person with

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.

Researcher

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.

The researcher should have some basic way of determining if the person has the mental capacity to make an informed decision. If the potential subject/participant appears not to have capacity (and if this has not been recognised previously), then the consumer's responsible clinician and/or next of kin should be notified. The researcher should not determine participation in research if the person has a known lack of capacity to make informed decsions.

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 Actived EPOA/Welfard Gua
2 The consumers identificatic
3 Provider not involved in the
4 Researcher for 'opt out' onl

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.

Thank your for providing the opportunity to contribute to this important consultation issue.

Please state your name

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 27 April 2017 at 7:17pm | Completed on 27 April 2017 at 8:01pm

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.

Ethical approval of this research would ensure it is deemed valuable for all consumers, whether they could consent or not. Many people with sepsis could not consent regardless of their previous health. We would want our designated next of kin (or support person) to be informed and to help with the decision to be included

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 per above, it would be appropriate to have the consumers designated next of kin or support person help with decision making at a time when the consumer could not make that decision.

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

It would be imperative that the consumer be informed following if they regain capacity so that they have the opportunity to understand the research, ask for results from the study and to decide against using their data 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.

People with dementia have the right to contribute to research if they would like to. Mental capacity is not black and white, but rather runs along a continuum. Many people with dementia can make informed choices about being part of research if what is

involved is clearly explained, but could not make more complex decisions such as those regarding finance. The consumer with dementia should also designate a next of kin or support person they trust to help them with this decision making.

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.

Ethical approval of this research would ensure it is deemed valuable for all consumers, whether they could consent or not. Many people with sepsis could not consent regardless of their previous health. I would want my designated next of kin (or support person) to be informed and to help with the decision to be included.

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.

It is the same as the answer to C.2, People with intellectual disability have the right to contribute to research if they would like to. Mental capacity is not black and white, but rather runs along a continuum. Many people with intellectual disability can make informed choices about being part of research if what is involved is clearly explained, but could not make more complex decisions such as those regarding finance. The consumer with intellectual disability should also designate a next of kin or support person they trust to help them with this decision making.

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.

Often the consumer may have a conflictual relationship with family members, or family members have conflictual relationships among themselves. The consumer should be asked whom they would designated as their trusted next of kin or support person to help them make decisions. If the consumer is unable to indicate their preference to be included in research or a trusted next of kin or support person at all, then only designated and activated EPOA or welfare guardian should be used to obtain consent.

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.

Exclusion from research of otherwise eligible persons with cognitive impairment for example (or with other health issues that fluctuate) whether or not they lack capacity to consent is discriminatory and violates ethical principle of justice [1]. People with cognitive impairment, for any reason, are entitled to have opportunities to participate in research. Furthermore, such exclusion can further exacerbate already existing vulnerabilities by further marginalising people [2]. Research designs need to seek to maximize opportunities for inclusion of people [3]. This translates as extending opportunities for informed consent based on information provided beyond the written word. For example, using visual information, audio information, use of artefacts and as stated on page 11: The information must be communicated effectively in a form, language and manner that enables the consumer to understand it. This is contradictory to the later statement on page 12: Once the consumer has been informed appropriately, he or she must provide written informed consent excluding people who are unable to write for any reason. Restrictions should apply only if it is clear that the design of the research including the consent process is evaluated by an approved ethics committee as not being appropriate for participants and in relation to the aim of the research.

[1] Alzheimer's Australia 2004, 'Research consent for cognitively impaired adults' recommendations for institutional review boards and investigators, Alzheimer's Disease and Associated Disorders, vol. 18, no. 3

[2] Dewing, J 2007, 'Participatory research: a method for process consent with persons who have dementia', Dementia, vol. 6, no. 1, pp. 11-25

[3] Murphy, K, Jordan, F, Hunter, A, Cooney, A & Casey, D 2014, 'Articulating the strategies for maximizing the inclusion of people with dementia in qualitative research studies', Dementia, vol. 0, pp. 1-26

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 should be aware however that research methodologies are not limited to Quantitative research i.e. the current assumption of the HDC that research methods are either observational or interventional is problematic in and of itself. That is, this assumption does not maximise the needs of people who may have difficulty providing consent potentially going against the very principle stated on page 8 of the consultation document "nothing about us without us" In other words, Informed consent is not a fixed and static event but rather a dynamic and ongoing social process.

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

Even if there is doubt about the reason for dissent or refusal, the researcher needs to assume that a person does not wish to participate and in keeping with ethical and moral principles of avoidance of coercion. As outlined above however, the law should be worded in such a way as not to risk further marginalising vulnerable people by assuming that expression of dissent or refusal is final and definite. That is by viewing informed consent as a one off static event rather than an ongoing process. See for example the method of process consent outlined by Jan Dewing [2].

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 should be possible under the law under specific circumstances deemed appropriate by an ethics committee.

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 is not ethically justifiable to exclude people from the opportunity to participate in research both at the level of the individual and the level of society.

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, the premise that most research with incompetent participants is uncertain and/or does not benefit a particular participant is highly problematic. There is evidence to suggest in our own field of gerontology and palliative care research that people involved in research often receive better care than those who don't as described on page 15: inclusion benefit, which is where a consumer benefits from being enrolled in research because he or she receives better monitoring and care than is received through standard care, or is helped by participating in a qualitative research process, such as an interview. For participants reaching the end of life, this is highly significant. For these people participating in research may result in improved symptom management and end of life care. These experiences can be enduring for family members who have to live on after the death of the person. This may be particularly critical for example, for someone with a potentially reversible delirium for whom being involved in the research improves quality of time and may even extends time for a person, family and whanau to discuss and deal with unfinished business. For someone with advanced dementia cared for in an ARC setting, being involved in research may mean increased interactions and engagement with others. For example, studies researching non-pharmacological interventions for behavioural Psychological Symptoms of Dementia have highlighted that engagement in and of itself appears to be the significant factor in the success of any intervention.

Further, there may be certain circumstances to carry out research with people who are unable to consent on the basis that the research may be part of 'usual practice' and do no harm to the individual but may benefit their family, whanau and/or 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	an ethics committee should
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.

In keeping with the law in other countries and highlighted in the consultation document, this would seem a reasonable approach so that research ethics might be evaluated in context of the research and its application and population rather than on a blanket rule while also providing a safeguard. This would require ongoing monitoring of the make up and standards of human research ethics committees.

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?

As the consultation document highlights (Page 15), the current 'best interests' test: does not provide for any consideration of the potential
for advances in knowledge that may benefit other people. Further it appears to privilege the decision-making of clinicians rather than participants and the public and does not account for inclusion benefit.

In this instance where the benefit is unclear, it would be appropriate for a proxy consent process to be developed if the person does not have the capacity to judge if it would be in their best interest. This should only apply If the person without capacity to consent has legally designated and activated Endursing Power of Attorney (EPOA) for Health and Welfare. The EPOA is legally bound to make decisions for the person unable to consent that are in best interests of the those unable to make informed decisions. It would unethical to ask anyone to participate in research that would be harmful to them whether they have the mental capacity or not to consent.

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 NZ law needs to account for a more socially nuanced concept of informed consent that minimises the risk of a single individual or health care provider/ other professional deciding on behalf of a person and that accounts for cultural context in terms of autonomy and decision-making.

As discussed in question 7.2, the law should accommodate ways for a decision to be made to participate in research by the designated and activated EPOA for the person unable to consent.

'Best interests' should not be decided by one person or one health care provider alone.

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.

Only when the EPOA is legally designated and activated.

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.

when nominated by the incompetent consumer as their substitute decision-maker through an EPOA.

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.

The consumer's responsible clinician (such as a GP, Nurse Practioner or specialist in the area that would have expertise in determining capacity such as mental health, geriatrics or palliative care can indicate that they would not assess the person as having the capacity to make an informed choice. If the person is deemed to lack to the capacity, then there should be a provision for the legally designated EPOA to be able make a decision based on what would be in the best interest of the person with

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.

Researcher

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.

The researcher should have some basic way of determining if the person has the mental capacity to make an informed decision. If the potential subject/participant appears not to have capacity (and if this has not been recognised previously), then the consumer's responsible clinician and/or next of kin should be notified. The researcher should not determine participation in research if the person has a known lack of capacity to make informed decsions.

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 Actived EPOA/Welfard Gua
2 The consumers identificatic
3 Provider not involved in the
4 Researcher for 'opt out' onl

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.

Thank your for providing the opportunity to contribute to this important consultation issue.

Please state your name

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 28 April 2017 at 10:34am | Completed on 28 April 2017 at 11:18am

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.

benefit to others
low risk to me as subject
non-invasive testing

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 clinically accepted approved treatments with low risk

Patients have a right to a reasonable standard of care. That right has a corresponding obligation - arguably there is an obligation for clinicians to conduct research to find out what the standard of care should be, based on evidence rather than surgeon preference (which could be influenced by the company selling the product)

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

No such thing. An analogy would be having sex and then asking your partner for consent.

The preferable view is two stage:
1. Research without consent (modified right 7(4) which could take into account others' interests); followed by
2. informed consent once patient able to consent (obviously for the capacity group only).

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.

increased rate of dementia in society is leading to an increased knowledge of how to manage people with it.
potentifial to increase quality of care
inclusion benefit

BUT would want pts who become distressed withdrawn from the study and for that data to be included in the study.

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.

risk too high, benefit unknown.

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

inadequate for a trial with the potential for such bad 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.

would need to knwo more about the % of suicide risk.
benefits of the drug are unknown
drug unavailable so even if cognition did improve it would not be a permanent benefit which could cause harm to the patient

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.

risk too high
benefit illusory
family may not have the patient's best interests at heart - many do not

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 they are patients too - with the right to be involved in research, especially if it is research that could offer benefit to them.

not including them in research has the potential to give distorted 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.

no other group that can be studied

minimal 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.

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

could be involuntary/reflex action - would need to have clinical input for each case

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 doesnt make sense.

You cannot consent after something has happened. All you can do is say you would have consented had you been asked. but because you were incompetent, you could not be asked. Therefore that part of the research was conducted without consent and a legal justification should be found for it. Easy if 7(4) can be satisfied and not if not.

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.

extra safeguard of vulnerable members of society. ECs in theory will not be conflicted - not always the case with 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?

best equal interests

risk and burden thresholds

7.3 Please state the reasons you formed this view.

currently a lot of good research cannot proceed because of the requirement that inclusion is in the particular patients best interests.

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
- [ ] 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.

- [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/WG
2 family
3 provider not involved
4
5

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

unsure whether the researcher should be involved as they could be conflicted

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.

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 26 March 2017 at 12:20pm | Completed on 28 April 2017 at 1:13pm

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

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.

Roche Products New Zealand Ltd welcomes this review of would like the HDC to consider the following 3 points

1. Right 7(4) - Code of Health and Disability Services indicates research can be considered if this is in the best interests of the individual. Most clinical trials involving the research of new products are designed with equipoise where the potential of the new product has yet to be established. Therefore, it can't be claimed that trial participation is always in the best interests of an individual. This element prevents NZ patients and researchers being involved in clinical trials of potential new and innovative products. This also effectively prohibits patient access to treatments through clinical trials where no other therapeutic options are available.

2. Consideration should be given to whether advanced consent has a place in clinical trials. In particular, this could enhance the understanding of the wishes of patients with progressive diseases. A solution could be that the initial process of consenting to participate in a clinical trial forms part of the patient's advanced care plan.

3. Please be aware and consider the impact of Privacy Rule No.2 under the Health Information Privacy Code 1994. If in the future consent is able to be provided by an authorised responsible person, it should be clear that this consent is applicable and aligned with the relevant aspects of the Health and Information Privacy Code.

Please state your name

Organisation (if applicable)

Roche Products 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.

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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 28 April 2017 at 12:19pm | Completed on 28 April 2017 at 2:00pm

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.

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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.

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

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
Research with this group of people is important as they are the most vulnerable and they have a right to the best health outcomes possible.
Without research, conditions that may or may not related directly to the reasons for a person's incapacity to consent cannot be adequately explored. In addition, current practice cannot be adequately researched.

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

Assessment of the degree of benefit to this person and others with a similar condition
Assessment of the risk of harm for this person and other research participants
Evaluation of current practice

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

Assessment would be difficult and would require the involvement of the people who know that person very well. Identifying that person is not without difficulties

The principle should be that the person is, in a meaningful manner, 'consulted' and if there is clear refusal to the research element then that 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.

Delayed consent (following some form of initial proxy consent by another) meets criteria related to informed consent being an ongoing process rather than a single one off agreement. It also supports the principles of participation and dignity

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 this would be best practice, some research cannot be undertaken on a group of competent 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.

Not all benefits (or risks) can be ascertained at the outset of a study
Many intervention study research designs of a high quality require comparison/control groups
Where possible, after data analysis, a beneficial intervention can also be offered to the control group members

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?	Priority will vary depending

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.

Independent, formal review should be a requirement, especially with participants who are unable to give consent.
This is congruent with the principle of protection.
In addition, for maximum benefit from research for other groups of consumers the results need to be disseminated. Few studies can now be published without prior formal ethical 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?

Risk and burden thresholds, but no benefit threshold

7.3 Please state the reasons you formed this view.

The combination of approaches seems necessary to balance the protection of individual participants while being expansive enough to not unduly limit research which may have significant positive outcomes

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.***

- [ ] 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.

While involving family and whanau may be appropriate in many circumstances it also adds additional complexity as there may be no collective consensus, family may not include the authorized representative, and family and whanau do not automatically act in the person's best interests.

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.

The clinician role is often to provide advice to the researcher as to the person's capacity to consent and be involved in the research processes.

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.

If the clinician has specific knowledge of how that research may have additional risks for this specific person

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.

Individual circumstances and contexts would make it difficult to rank, however the researcher's role should be limited in this step

Final comments

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

Currently, there is little consideration of 'observational studies' that may use qualitative methods. Observational studies may place a significant burden on participants and families (as well as having some indirect benefits that are not usually considered).

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 28 April 2017 at 12:19pm | Completed on 28 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.

It is in the interest of our patients and the health of the nation that such data is responsibly and anonymously collated to improve future healthcare for all. We see minimal/no harms to participants in this research and if participants survive this event it is conceivable that they may have another serious infection in the future and therefore benefit directly from this research.

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.

Currently the opinion of the neurosurgeon alone would determine which treatment patients received.

Although most doctors think they are recommending products in the patient's interest, they may be unduly influenced by the manufacturers of such products either consciously or subconsciously.

We would rather people were given products that were proven in well designed studies to be better or cheaper than other products (that were equally as good) and therefore would like to be part of research that helped to provide a higher quality of evidence than one doctor's opinion.

It is in the interest of our patients and the health of the nation that such data is responsibly and anonymously collated to improve future healthcare for all.

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

It can be argued that delayed consent is counter-intuitive regarding autonomy as treatments will have already been given and the participant didn't get a say in that decision. However it can also be argued that it does to some degree respect participant's autonomy, as they are firstly informed that they are involved in a study and secondly that they have the power to withdraw or continue their involvement in that study.

Importantly delayed consent allows for participants who would have otherwise been unable to participate due to the severity of their illness to participate and accrue the benefits of the research. This also strengthens the quality of information attained by the research which will be able to be generalised to the most unwell people.

People should not be unfairly marginalised and disadvantaged by exclusion from well designed minimal risk emergency and resuscitation research due to the severity of their illness or injury.

We note that delayed consent has already been used successfully in several major studies conducted in Emergency and ICU settings in NZ with very low rates of subsequent refusal to use data.

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.

We think that people with impaired capacity should not be unfairly marginalised and miss out on the benefits of participating in the creation of on high quality evidence about their condition.

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 believe that there is true equipoise in this scenario and that it would be unethical not to conduct research to determine the truth in this setting. In this setting the participants are dead and therefore the potential for harm by being in the research is minimal (being in the research will not make you 'more' dead), although we acknowledge that survival with a severe neurological deficit may be regarded by some as worse than death. If there is concern that the current treatment with adrenaline may increase this bad outcome it is imperative that research is done to determine the truth.

People who survive cardiac arrest may suffer another cardiac arrest in the future and would therefore benefit directly from participation.

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

Our members believed that the 'opt out' option was a good one but were concerned about the practical application of such an option. Public debate about consent processes for Emergency Research should be encouraged in NZ.

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.

Members of our group had differing opinions on this issue so we are unable to provide a group consensus response.

One thought that people with Down syndrome should be able to be part of this research if appropriate consultation took place with whanau / caregivers.

Another thought that participants may have materially benefited from participation and imposing the burden of written informed consent on them (with reduced capacity to understand the information) would likely lead to systematically and unfairly excluding them from the research.

Others thought that as the drug would not be made available after the trial was competed so there is no potential for long term benefit for the participants and that as a result this proposed research was unethical (analagous to the historical situation where expensive HIV treatments were studied in Africa then were only practically available in the West due to cost).

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.

Again our group had differing views on this issue (between Unsure and Yes in response to the question).

One felt that sufficient protection would be given, while others expressed the following concerns
1. that prior research has suggested that there may be a disconnect between the surrogate's views and the participant's views with respect to consent
2. As long as there is no doubt that the surrogate is acting the best interests of the participant.

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.

It does not make sense that clinicians are allowed to give potentially harmful or expensive treatments that have not been shown to be beneficial in high quality studies, while at the same time we are not able to conduct studies which would demonstrate whether these treatments are beneficial or 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 condition / persons for whom the research is proposed is such that informed consent is not possible to be obtained and the study is in the public good.

The study should not be for the sole benefit of a commercial entity (private company) and clinicians conducting the research should not benefit directly from enrolling the participants.

Studies sponsored by commercial entities in which clinicians or their departments are paid (per participant or otherwise) to enroll participants should not be allowed to enroll incapacitated participants. In this setting the clinicians should definitely not be the decision makers with respect to enrolling participants as they have a financial interest which may outweigh their objectivity about whether it is in the best interest of the patient to participate

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 does not make sense to have one rule for one group and another rule for another group. From a research participant's perspective what is the difference who the researcher works for?

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 the closest we can come to finding out what the impaired individual actually thinks. Some people just don't like the thought of being in a study and this is their right.

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.

This is a reasonable suggestion and has already happened in several studies conducted in New Zealand, with very low rates of subsequent denial of consent to use information. In this way people with the most serious illnesses are not denied the opportunity to contribute to knowledge and potential selection bias in studies towards those who are less unwell will be avoided. This way the quality of research and generalisabilty of the research results will be improved and those who are most severe illness and injury are not systematically denied the right to participate in high quality public good research

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 would be difficult to apply as a blanket rule. It may be valid for some intervention studies but for other intervention studies it may be that potential benefits or harms may only be evident in those with more severe illness or injury who are unable to consent, so research on those who are able to consent may not be relevant or transferable. When there is minimal risk to participants (eg observational research) then there should be no such requirement. The practicality of such a requirement is unclear.

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 situation for all research into resuscitation for severe illness and injury. Currently we can treat such people with treatments that have not been proven to be safe or effective, yet we are not able to conduct research to determine what the best and safest treatments are, which does not make sense.

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 people being studied s
2	The research should be for
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 is very important that we build in protections for vulnerable people when it comes to research participation. Ethics committees are the logical group to provide that protection and for research where informed consent is not possible (eg resuscitation from cardiac arrest) then the ethics committee may be a surrogate decision maker.

In NZ currently there has been a centralisation of the HDECs and in parallel with this, the types of research which are currently considered eligible for full committee assessment have been dramatically reduced.
In many parts of New Zealand there is great confusion as to who to go to, to obtain appropriate ethical review.
We believe that all studies should undergo some sort of review but that there will be varying levels of review required depending on the type of study. Urgent clarification is required on this issue and should be applied consistently across the country.

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?

There should be a threshold test such that by participating in the research the person is at no greater risk of harm or benefit than if they didn't participate (ie - there is equipoise between the treatments).

7.3 Please state the reasons you formed this view.

It is illogical to allow doctors to give people unproven treatments and at the same time prevent them from doing studies to find out which treatments are best.

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

Decision-makers.

EPOA

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?
- [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.

EPOA
Whanau / family

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
- [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.

Ethics 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.***

- [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.)
- [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.

EPOA
Whanau

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
- [x] Other

Additional comment.

An ethics committee may grant a waiver of consent in the absence of other decision makers for research in emergency situations for incompetent persons for studies that were minimal risk and were for the public good (not commercially sponsored / funded studies).

This could be supplemented by a deferred consent process for either participants or relative / whanau.

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 Whanau
3 Provider not involved

4 Ethics Committee

5 Researcher

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

Clinicians or Researchers should not be the decision makers when they or their department / hospital have a financial interest in enrolling participants (ie they are being paid per participant by a company to do a study on that company's product).

This is different to the situation where reasonable costs of the research are being met by a competitive public good research grant (HRC grant or similar), in which case there should be no per-participant payment but a general payment to cover the reasonable costs of the research.

Final comments

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

I have submitted this collective response on behalf of the New Zealand Emergency Medicine Network, a collaboration of Emergency Medicine doctors, nurses and patients who are interested in emergency research which I currently chair (https://www.nzemn.org/).

I and other individual members of the network have also separately responded to the survey as our individual views may differ slightly for some questions. I have endeavoured to represent the group's views in our consensus response.

I would also like to draw the Commissioner's attention to the following systematic review which concisely summarises the world literature on this topic:

"Key stakeholder perceptions about consent to participate in acute illness research. Gobat et al, Trials (2015) 16:591."

Please state your name

Dr Peter Jones

Organisation (if applicable)

On behalf of the New Zealand Emergency Medicine Network

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 28 April 2017 at 9:13am | Completed on 28 April 2017 at 2:26pm

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 will not be amended and the moments of discomfort (if I was able to feel them) due to a few extra tests are neither here nor there in the scheme of things.

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 approved. I would get one or the other anyway. Where there are two products available it must surely be a good thing to study, compare and contrast them.

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

I am uncomfortable about delayed consent. The people I support who are not able to give their informed consent now, are never likely to be able to. However, as long as there are safeguards in place governing the types of research allowed without informed consent (see answer to 1.2 later), it may not much matter.

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.

Psychosocial needs sounds much more exciting that the usual task-focused stuff, but even if I landed up in the conventional care group, the extra attention has got to be worth it, especially as I could always tell them to sod off if it got a bit much, and they'd have to respect that.

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 a friend who is alive only because she was given a jab of adrenaline. I would not be in the slightest bit interested in being part of a study where I may be given salt water when my life was in danger.

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

I appreciate Dr D's difficulties, but this kind of research should only be done with people who are able to give informed consent. People should not be placed in the position where they have to opt out of something that could have serious ramifications if they forget or don't get round to doing so. I do not agree with the opt out process in this situation. There must be some other way of assessing the use of adrenaline.

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 is far too invasive: both in terms of taking a drug with the potential to cause a significant and undesirable side effect, and in terms of 6 hour assessments. It is not known if there will be any beneficial effect, (we are not told the results of the study on people without Down Syndrome), and the study has a whiff of the unnnecessary guinea pig about 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.

While there's probably always going to be the rare exception, my experience of family/whaanau/caregivers is that they generally bend over backwards to support and look after the interests of people who are unable to give informed consent. They are generally excellent advocates, genuinely interested in the wellbeing of the person, and fierce defenders of people's rights.

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 research is to be supported, but only when the criteria in 1.2 are met. We are crying out for more research, but it has to be done with respect shown to the sanctity of the individual.
There is plenty of research urgently needed, for instance in relation to people with Learning Disabilities, which could be done with people able to consent. The differences in life expectancies (males with LDs 59.7 years cf males without LDs 78.4 years, and females with LDs 59.5 cf 82.4 - Ministry of Health 2011) indicate that something is very wrong and needs addressing.

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

- When the research would benefit that person or someone else
- and when there's no one who can consent available
- and when participation would leave that person in the same or better situation than before
- and when the research is observational and not interventional. Extra tests on blood or urine samples that would have been taken anyway are fine, but extra blood samples being taken for the purposes of the research are not.
- and when a change in facial expression, sound or gesture that could reasonably be interpreted as showing dissent is acted on and that person is removed from the study
- and when the research has Ethics Committee approval and the law applies to all types of 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.

It makes sense that all research should be covered by the same law, for consistency's sake.

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 who are able to give informed consent are also able to withdraw from the research if they are not happy about something and don't want to continue with it. The same should apply for people who are not able to give informed consent. The input of people who know the person well is important here, in interpreting their facial expressions, sounds, gestures and so on.

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 doesn't sit right, to consent to something that's already happened. It would make a nonsense of the informed consent process to allow this. Advance consent, on the other hand, is fine.

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 is grossly unfair to involve someone who can't consent, if there are others who can consent.

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.

As long as the provisos in 1.2 are in place I can't see any reason for someone who is not able to consent not being included in studies that benefit humanity. It would be no skin off their nose, and they would be doing something good for the community in the same ways as others do.

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 Committees provide an important protection for people who are unable to give informed 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?

I would however, like the best interests test to be extended to include benefits to other people, as long as all the other safeguards apply.

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 EPOA or welfare guardian
2 Family/whaanau
3 Provider not involved in the
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.

Thank you for the opportunity to give my views.

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 28 April 2017 at 12:48pm | Completed on 28 April 2017 at 2:35pm

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 example is about managing a serious health condition. The research would not affect the patient's treatment and would not have any negative impact on them.

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 two drugs had gone through clinical approval, so this research was not medical experimentation in the sense of determining drug safety. And as the evidence does not give preference to one drug over another, the patient would experience neither a benefit nor a disadvantage.

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

Only applicable in urgent and emergency situations, and not appropriate for planned 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.

Consent can be determined for people with cognitive impairment as a process of ongoing monitoring of what happens as the result of their involvement in the research; and not necessarily a black/white informed written consent in advance. If the patient shows distress at being involved, they should immediately be removed. This is the responsbility of the researcher and the care

support system involved.

In addition, this specific treatment shown is assumed to be in addition to the ordinary care and support the patient gets, so they should be no worse off unless the change or the new treatment itself is not welcomed by the patient.

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 invasiveness of this treatment and the possibility of serious consequences suggests that alternative ways of testing the hypothesis should be explored.

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

This is not reliable and assumes everyone has access to perfect information about the research. Opt out would only be responsible to use in situations where there was a guaranteed ability to make a choice, for example if driver licensing system changed to an opt out for identification as an organ donor and a decision was needed during application.

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.

Having Down's syndrome is not a medical condition that should be treated by medication. This proposal assumes a negative view of people with Down's syndrome. There does not seem to be any positive benefit from the drug for people with Down's 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.

This treatment appears to be a form of medical experimentation that is not in the best interests of the people with Down's syndrome. The opinion of carers/family members will not alter the research and cannot displace the responsibility to support the rights of people with Down's syndrome themselves.

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 limited circumstances. I agreed with the English and Scottish approaches, where any research must be ethically approved mandatory, and there should be ongoing monitoring by people independent of the research to determine any distress or expression by the patient that indicates their willingness to withdraw from the research. Such research should indicate a clear and positive benefit for people, whether it includes the patient directly or 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 patient who are non-consenting should be supported by independent advocates/people who know them so there is ongoing monitoring through out the research to ascertain whether the patient expresses their intention to withdraw. Any identified expression should be acted on immediately.

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.

All research that impacts on people who are not able to independent consent to participate should be covered by the same rules and safeguards.

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

Consistent with the UNCRPD and modern approach to recognisting the rights, will and perferences of disabled people on an equal basis with non-disabled people, any expression of dissent must be acted on. It is important that an independent advocate/someone who knows the patient is present to determine consent/dissent, even if the communicate is through physical behaviour.

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 not consent.

It can only apply during urgent and emergency situations, which is already covered under duty of care in the code of rights.

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 risk of negative impacts on incompetent persons is too great to bare. The State has an obligation to protect those who cannot protect themselves. The chance that an incompetent person is not able to communicate or express pain or other negative consequences from research is too much to risk, regardless of the benefits.

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 balanced approach should be taken. Any involvement of incompetent persons must be accompanied by safeguards to ensure their ongoing assent at being involved. This is often through the involvement of independent advocates/support people who know the patient really well.

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	Has signficant benefits to o
2	Not exclude benefitting the
3	Formal and mandatory ethr
4	Safeguards in place for the
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.

Formal ethics approval would give an alternative look at whether the research's methods were necessary, and determine that safeguards are 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?

Who is determining the best interests, and how does it relate to the incompetent patients themselves? There should be a high bar to cross before any research is conducted on people who are incompetent to preserve their dignity and safety. Researchers must prove that the involvement of people who are incompetent is necessary and not just desirable. There should also be clear benefits gained from the research, which does not harm the incompetenet persons.

7.3 Please state the reasons you formed this view.

The risk of harm and maltreatment is too great to allow open participation in research for people who are incompetent, without strong safeguards in place.

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.

More attention in law should be to recognising the rights, will and preference of people, and for its expression to be acted on, consistent with the UNCRPD.

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.

Every person can communicate. Some people may not communicate intentially. However, such a person may be able to express preferences that other people, who know them well, can understand and therefore can act upon. More attention should be put to support people who are ordinarily deemed incompentent so their expressions of will and preference can be recongised and acted upon. The more people who know an incompetent person the better will be the understanding of their communication.

Peope who are attorneys or guardians may not themselves have a good understanding or relationship wiht the incompetent person.

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.

The views of family/whanau are a critical input to decision making about an incompetent person. Bt they should not form the whole position about an incompentent person. Family members will likely know the incompetenet person well.

Additional comment.

It is also valuable to involve others who knows the incompetent person, such as friends, to inform the incompetent's person's decision making, or at least monitoring of any expression of dissent.

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.

People who are close in relationship with the incompetent person and who knows them well. Particularly if they understand the communication style of the incompetent person and can help with others to understand expressions of will and preference.

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 A group of people who kno
2
3
4
5

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

It is preferable that a group of people who know the incompetent person well should be involved together in determining they should particiate.

Final comments

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

There is a lot to be learned from over seas on finding a different balance for NZ on benefits from inclusion in research, so long as there are adqueate safeguards in place to identify any expression of dissent.

All research should abide by similar mandatory approach.

Guidelines could be developed to enable better understanding of research and the benefits/risks of being involved.

Any change must be consistent with the UNCRPD.

Disabled people and their representatives should be involved in the research planning and implementation as much as practically possible.

Please state your name

Organisation (if applicable)

Office for Disability Issues, Ministry of Social Development

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 28 April 2017 at 10:10am | Completed on 28 April 2017 at 2:49pm

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.

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

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.

New Zealanders for Health Research (NZHR) was formally established in November 2015 to lift investment in health research from all sources including government, industry and philanthropy. Our members include University of Otago, Massey University, Victoria University, the Malaghan Institute, Merck, Sharp and Dohme, Roche, AbbVie, CureKids, Auckland Medical Research Foundation, and the Cawthron Institute.

Our ultimate aim is to achieve improved prosperity and health for all New Zealanders, and we believe that well-resourced, appropriately directed high quality health research is a key contributor to these outcomes. We therefore have an interest in seeing the removal of unreasonable or unnecessary constraints on New Zealand's ability and capacity to undertake health research. In principle we support the permissibility of research being undertaken on those unable to give consent where there is demonstrated benefit to others provided that the wellbeing of those unable to consent is not compromised, and that a mandatory independent consenting "on behalf" process is established.

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

NZHR's position is that research on a person who is unable to give consent should be able to take place if:
- participation in the research is in that person's best interests (as at present), or
- participation in the research can be demonstrated through a peer review process to be of benefit to others, and
- participation in the research will not compromise care delivery to, or health outcomes or wellbeing of the person who is unable to give consent, and

- consent is given on behalf of the person who is unable to give consent, and
- such consent is given by somebody who is appropriately qualified and/or authorised to do so and is independent of both the researcher and that person's health care provider(s)
- the research is unable to be undertaken effectively with people who can give consent, and
- the family or other authorised representative of the person unable to give consent have no reason to believe that the prospective participant would have declined to consent had they been able to, and
- there is no explicit or implicit objection from 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

Any indication of non-consent should be respected, and the research should not proceed.

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 cannot be given or withheld retrospectively. However, consent to continue participating should be obtained if the study is continuing, and irrespective of whether the research is continuing non consenting participants should, upon becoming competent, have the opportunity to have data collected from them while they were incompetent removed .

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.

NZHR believes that consenting on behalf of participants who are unable to give consent for themselves should be both mandatory and undertaken independently of the researcher or the person's health care providers. Ethics committee approval provides an impartial mechanism for ensuring that the research is important and potentially beneficial to others, and minimising the risk of undertaking research which the incompetent person would not have otherwise consented to.

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 principal criterion should be that the consumer will not be worse off as a result of participating in the 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.*

- [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.)
- [ ] 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
Family

Additional comment.

A decision making provider should not be directly involved in the care of the patient unable to give consent

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 guardian
2 Family
3 provider not involved in the
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

Chris Higgins

Organisation (if applicable)

New Zealanders for Health Research

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.

Happy for the information to be released.

Chris Higgins
Chief Executive
NZHR

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 28 April 2017 at 2:12pm | Completed on 28 April 2017 at 2:53pm

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.

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

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. It is our contention that "low risk – low burden" research could safely proceed with adult participants who are considered to be unable to provide informed consent. This response is qualified by stating that all such research should be subject to rigorous ethical review. From a social research perspective, researchers have been able to learn a lot about the lives of people with complex impairments through observational, often ethnographic research. Many of the individuals who have taken part in such research have not been able to provide informed consent in the conventional sense but have contributed to improved understanding, supports and services related to other people in similar circumstances in the future. In some cases, their involvement in research of this nature has led to an immediate improvement in support practice. In summary, allowing low-risk / low burden research with people who are unable to provide informed consent in some, carefully controlled contexts, facilitates greater understanding of key issues and questions. With specific reference to people with disability, restricting all opportunities to conduct research on their perspectives, experiences, and social realities could lead to further marginalisation.

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 noted above, research that utilises low-risk methodologies (typically observational research) and creates a low burden for participants should be allowed to proceed in some circumstances. Most critically however, all research involving people who are unable to consent should be assessed by an independent, accredited ethics committee, for both scientific validity and responsiveness to ethical considerations. In the case that a person is unable to provide informed consent facilitated decision making should be applied. Facilitated decision making is a process, a process whereby other people who know the focus person well should be applied. While others ultimately provide the consent on another person's behalf, they do so in keeping with their best judgment of what the person's will and preference would likely be. Again, approval should only be granted if the research is non-experimental, low risk, and low burden.

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.

We hold the perspective that all proposed research projects should undergo consistent and rigorous ethical procedures to safeguard ethical and respectful practice. The Code in its current format limits the potential to pursue valuable research with participants who cannot provide informed consent. In our experience, the Code provisions have a threshold that would have excluded a lot of social research (conducted by non-health and disability providers) that has led, either directly or indirectly to increased knowledge of particular health conditions and impairments, and to important improvements in health care and disability supports and services. In short, this research has led to revisions of policy and practice that has contributed to improving the overall welfare of marginalised populations. The H&D Code precludes health and disability providers to conduct scientifically rigorous, low-risk, low-burden social research, and creates a sense of unease for researchers who are not subject to the Code and therefore legally able to pursue such research. That is, researchers not employed within health and disability services recognise an inequity in practice that has the potential to be to the disadvantage of people whose lives we seek to improve through 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

It is important that researchers see informed consent as a process, not a discrete act, and continue to check in with participants throughout the research. Linked to this, even if people are able to communicate verbally, it is critical that researchers remain attuned to signs of assent or dissent within research. In most circumstances, persons who are regarded as not being able to provide informed consent can provide verbal, body language, and other expressive cues that indicate whether they are comfortable with the research and its processes. These expressions and signs are present in research processes with participants, irrespective of competence. It is through non-verbal (body language, alternative communication, etc) and verbal expressions that people can convey their interests, will, and preference.

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.

We do not think that the law should be changed to enable delayed consent. Delayed consent does not provide participants options for meaningful choice in whether they participate in research.

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. However, we would like to reiterate our earlier view that low risk, low burden research should be permitted on the grounds that we need to build a body of evidence that will necessarily require the participation and knowledge of people who are regarded as unable to provide informed consent. It is important that people who are regarded as unable to provide informed consent are still meaningfully included in research so that evidence can inform law, policy, and practice.

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.

Best interests within research is difficult to meaningfully ascertain, and as a result it could be interpreted that no research can confidently be judged as meeting the standards of a best interests test. A necessary qualification to this view is that that research should be consistent with a participant's/potential participant's will and preferences. In the disability sphere The United Nations Convention on the Rights of Persons with Disabilities signposts a shift away from notions of "best interests" (that is other people making judgements what is best for someone else) to that of will and preference (whereby extensive effort is made to ascertain what the person would be likely to want). Many individuals who fall into the category of being unable to provide informed consent, are also now subject to the UNCRPD. Furthermore, a significant amount of social research (ethnography, narrative studies, etc) falls into the category of research that does provide not direct benefit, but is designed to contribute benefits to people with the same impairment or condition in future. As an organisation that conducts social research, we have seen the importance of such research in making changes in the future that counter the marginalisation people experience. Consideration of international legislation that has addressed this issue is recommended to inform the New Zealand context. Such legislation must align with the UNCRPD.

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	Low risk
2	Low burden
3	Observational methodology
4	Assessed by individuals kn
5	Focused on developing un
Any others?	Rigorous safeguards

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.

We believe that an external ethics process is important to ensure that researchers more actively consider the rationale for their research, and how to recognise and address ethical concerns. In order to do this, external, skilled ethics committees are required within the process to provide a safeguard against exploitation and / or abuse. We believe that key to such safeguards are highly and diversely-skilled ethics committees that include exploration of the scientific validity of a project under their scope. In our view, scientific validity (the suitability of the research methodology to the research aim or question) is a component of ethics.

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-burden criterion

7.3 Please state the reasons you formed this view.

Social (observational) research often has the purpose of countering the marginalisation of particular groups. Given the nature of this type of research, much would be unable to proceed under the best interests test. Many of the participants who have taken part in such research (people with disability) within the context of our own organisation place value on working towards improving society for marginalised people; therefore, we place value on research that could be beneficial in the future although it may not be directly beneficial to the research participant. However, our approach prioritises low-risk-burden research that is consistent with the ongoing will, preferences, and assent of individual participants.

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.

Vetoing and withholding consent powers can be useful for third-parties, so long as they prioritise the person's will and preference in those vetoing and consent decisions.

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.

All of the named decision-making contributors in the table could potentially be involved in decision-making as is compatible with a participant's will and preference. We are of the view that it is important that the person themselves are permitted to choose who they trust to best convey their interests, will, and preference and who is closest to them with regard to insight into their will and preference. The scope of people who can be involved in decision-making should extend further to friends and other close people, so to be consistent with the wider range of third-parties who factor as important in many people's lives. This is particularly pertinent with regard to people who are unable to consent.

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.

The ranking of decision-making contributors is contingent on the subjective assessment of the person themselves and who the person regards as better for advocating for their interests, will, and preference. In the case that a person is not able to convey this, facilitated decision making should be employed. As previously mentioned, facilitated decision making is a person-centred process involves all those people who know the person well, and who can contribute to decisions seen as most likely to be aligned with the person's will and preference.

Final comments

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

Please state your name

Brigit Mirfin-Veitch, Director

Organisation (if applicable)

Donald Beasley Insititute

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.

This submission expresses the general position of the Donald Beasley Institute and was developed in consultation and collaboration with all staff. For this reason, we have only answered the broad questions, and have not answered the questions relating to the individual cases.

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 10:35am | Completed on 28 April 2017 at 3:03pm

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.

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 presents a potential benefit for the person as well as producing valuable knowledge that could help many others. There is also minimal foreseeable risk to participants. However, participants need to have the ability to withdraw if they were able to give consent, as the study contains tests that would otherwise not be necessary.

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 clinically approved and commonly used, therefore participants in the study would expect to receive a level of care equivalent to non-participants. However, it would be essential that a robust review of the evidence was carried out and that there was consideration of a range of outcomes relevant to the client. Additionally, this research should only proceed with prior consent.

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

Delayed consent is never appropriate; consent is something which needs to be given before proceeding with research, otherwise people may experience harm retrospectively.

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 seems to be minimal risk to participants, which is outweighed by the potential benefits to participating in the research. Additional assessments are unobtrusive and the proposed research embraces the social model of disability and is seemingly aligned with dominant views across the NZ disability sector and consumer preferences for models of support. However, it would

be absolutely necessary to seek formal ethical approval before commencement as well as establishing clear processes and protocols for the intervention to stop if there is perceived harm to people involved. In this situation, there is also an opportunity to evaluate the impact of observations and assessments as it is likely that personal contact is likely to lead to a positive outcome. Consideration should also be given to first trialling the intervention on a group that is able to provide consent in order to build an evidence base.

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 not enough information given about what other type of care is being given and how risks are mitigated. Also, the potential harm appears to be life-threatening. No evidence has been presented from research involving cellular manipulation or trials involving mice or other animals, which seem to be a logical starting point before using vulnerable human subjects.

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

The opt-out process provides little or no protection for vulnerable people. A public awareness campaign provides no guarantee that people will be aware of the study and the potential risks. Consent should involve opting in and not out of research.

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 effects on people with Down syndrome are unknown. There needs to be more baseline data about the potential benefits and risks for participants and it seems logical to first conduct research with participants who have Down syndrome and are able to provide consent. Additionally, the research involves obtrusive testing which is likely to cause discomfort for participants.

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.

Suicide ideation is a serious side effect, especially as we don't fully understand the prevalence and impact of mental health issues for disabled people. It is unlikely that those consulted as part of the consent process will have expertise in this area to make an informed decision.

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 could directly benefit participants or provide benefit to others by gaining valuable knowledge around provision of intervention. Additionally some research poses little or no risk, such as observational studies. Partnership and participation, guiding principles upon which we base our work, conflict with uniform exclusion of disabled people from research that is accessible to other citizens.

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

--Research involving people who are unable to provide consent should be subject to review and approval to ensure minimisation of risk of harm for participants. This would apply to observational studies as well.
--A uniform, established process for gaining consent should be followed, see comments in 8.5
--Participants need to be able to opt-out at any point during the course of the study, with establish protocols, based on the person's unique presentation of disability, put in writing for each individual participant
--Information on informed consent, withdrawal and the impact of not taking part needs to be provided in a manner that is easily understood

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.

Common standards would provide clarity to researchers, participants, whānau and caregivers. Universal application of law and equal treatment for disabled people provides the most protection for vulnerable populations.

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 basic respect for a person's decision making ability. Expressly stating this in law ensures protection for people unable to verbally express themselves or who struggle with traditional means of communication.

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 never appropriate; consent is something which needs to be given before proceeding with research, otherwise people may experience harm retrospectively.

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.

Researchers should be held to the highest moral and ethical standards possible. Established law would provide the greatest degree of protection for vulnerable people.

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.

Disabled people share the same personality traits as their non-disabled peers. Some will highly safeguard privacy or be risk averse but many others will show a willingness to help others, make sacrifice or expose themselves to reasonable risk for the sake of a greater good. We need to avoid making broad generalisations about people or assume a default position. Altruism isn't unique to non-disabled people and, as with everything else, decisions need to be made on an individual basis.

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	People who receive or ben
2	People with the same cond
3	Whānau and local commur
4	People from the same cultu
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 seems to be a logical safeguard to protect vulnerable people from harm and codifying the process in law ensures universal application of standards.

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?

Formal ethical approval would be essential to ensure minimisation of risk or burden on the participant. The benefit threshold should also view the individual within the context of their community and not in isolation.

7.3 Please state the reasons you formed this view.

Focussing solely on the individual takes too narrow of a viewpoint and ignores important relationships and aspects of that person's personality as well as their cultural identity. The benefit threshold needs to take community into account and current parameters for determining 'best interest' fail to do this. This ignores the social context of the person, therefore a determination needs to be made about the potential benefit to the person/community vs the risk to the individual.

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.

There is a role for all of the potential decision makers when considering whether or not a person who is unable to provide consent should take part in research. We would advocate taking a team approach to forming this decision. Ideally, this would involve the disabled person, EPOA/ welfare guardian, whānau, provider not involved in research, service/ support provider or caregiver as well as researcher. If there is agreement from all involved, then participation should be allowed. In the instance of disagreement, it would be suggested to involve an independent advocate to act as the ultimate decision maker.

There is little guarantee that any one person listed (EPOA, welfare guardian, whānau, provider, researcher) is actually acting in the best interest of the disabled person. A team-based, consensus decision making process provides the best way of ensuring that the welfare of the person is prioritised and their individuality respected. A clear, established decision-making process for determining best interest would provide the best guarantee of protection for people unable to provide consent while also allowing opportunity for individual choice around participation.

Final comments

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

When considering responses to the case studies it is assumed that in cases where there is POA or someone who is able to provide consent, researchers would continue to utilise well-established practice already embedded in the PPPR Act.

Please state your name

John Vogenthaler, Project Manager on behalf of Robyn Shearer, Chief Executive Officer

Organisation (if applicable)

Te Pou o te Whakaaro Nui

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.

None of the responses are considered confidential.

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 8:42am | Completed on 28 April 2017 at 3:43pm

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 believe this would constitute a special case of research that is both valid and in the interests on the people receiving treatment.

When it comes to ethics often the issue is a balance of difference values, risks and harms. In this case we are providing a treatment as usual which has an unknown side effect for patients. It seems inconsistent that to collect data in a manner which would be consistent with treatment interventions for research is deemed unethical when a physician can order such tests in the interests of the patient. Especially given in this case the data gathered benefits the patient (identifying how much antibiotic loss) and the body of knowledge as a whole.

Yes there is a minor increase in inconvenience that the patients data is being used for study and the general risk associated with that, however because this directly informs a treatment that is in use and increases our body of knowledge in that area I believe it is ethical.

For example if the research did not include data useful for the interests of the patient currently or the study was only tangentially related to a treatment for example trialing a different antibiotic that wasn't approved as treatment as usual this would not be ethical.

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 most part this study seems unethical as there isn't really a clear reason to justify it. Although I selected unsure because the technically a patient could receive either treatment on the whims of a professional, which I find is inconsistent that which is deemed ethical for a medical professional treating to make an arbitrary decision is also deemed unethical to make for the purpose of research. In this case both treatments are likely choices for any given patient, the only issue is the potential risks of data handling etc.

However overall my main concern is the lack of rationale (to be fair this could be lack of information presented in this case-study), general knowledge increase doesn't justify the inconvenience of a patient, however if the knowledge gained directly informs the nature of the current treatment for patients. In the previous example of antibiotic loss through dialysis it could be argued to continue to treat people with an unknown side effect is more unethical than research, but in this case there appears to be no such risk.

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

For the most part I am against this form of consent, unless handled extremely sensitively. People in medical recovery are generally going to be unsettled by being informed they have been part of research and thus again impacted by said research.

If this were framed as we would like to use data gathered from your treatment which was conducted as per your best interest to inform research this may be more 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.

While I would be comfortable with this form of research personally I do have some concerns, for example whether best practice on dementia wards couldn't follow best practice from the current body of research already. I may be wrong but I'm confident there is enough research on the human condition to safely say that people requiring high levels of support have better quality of life when their support focuses on more than just immediate needs.

Again ethics must be considered as a balancing act of risks and benefits. If there wasn't a body of research in this area this could benefit the population greatly, including the participants themselves. The alternative being to continue receiving potentially sub-par treatment as usual. The difference between this research and the more emergency or within medical treatments of the other cases is this is concerned with the nature of people's supports for the rest of their lives. It seems counter-productive to allow support and treatment to be provided in an uninformed fashion because the intention is in the person's interests and not to be included in research that very much might enhance that person's best interest in a long term quality of life fashion.

However that all said, as the case-study suggests participants may be found who could consent. On a side note to exclude any adult who cannot verbally consent from research is perhaps exclusionary and essentially dooming certain populations to only rely on incidental research again which is a shame. I think in most cases consenting participants is the ethical approach, however consider that for people with life-long learning disabilities who cannot provide consent have an incredible amount of their lives decided without consent and in some respects need robust research to make being able to support them as empirically sound so rather than supporting people in what we think is in their best interests we can support them with evidence that the support is in their best interests.

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.

As the research is uncertain I an unable to form a view on the topic. I believe most people would be horrified at the prospect of being assigned to the placebo trial, however I am equally horrified at not having the data on a treatment as usual that could cause side effects.

Many people opt for the whatever saves a life in the immediate which is a fair stance, however again without the actual data it becomes hard to make an informed choice, for example if adrenaline increases immediate survival by 50% and risk of ongoing side-effects by 5% it would probably still be in everyone's best interest to continue using the treatment. However if this were

reversed the treatment would be questioned.

Language is very important, the majority of people would not want to have their emergency treatment withheld for research purposes, but equally I doubt people would want their emergency treatment to be uninformed and based on poor information, again because the research is deemed more unethical than a doctor doing what they 'think' is in their best interest

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

I'm not 100% against this practice, however I believe it should be an opt in process. It's unethical to automatically enroll people in research, but I think there is an option for proactive recruitment.

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 I remember this study and it was basically someone assumed that the performance enhancing nature of ritalin or a derivative could be used on people with ID to basically make some IQ gains, in terms of experimental rationale it was not particularly justified - I do not believe there was any particular prior evidence of benefit to participants, specific population or general knowledge.

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.

While significant others should always be consulted as per the HDC code of rights informed consent in general I believe the guidelines of the PPP&R act are suitably clear in terms of how to approach informed consent for people without capacity to communicate.

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 in certain cases it should be able to be performed if the following criteria are met:

- the research will directly inform treatment of that participant and reduce potential harms or unknowns of that treatment - i.e. the potential harms of research are justified by the potential harms of simply continuing treatment as usual.

- there is absolutely no other alternative for research in this area AND the current body of research justifies the increase as knowledge as it will prevent harm from standard treatments in the future

- all aspects of the research are designed to reduce harm and inconvenience to the participant, such as testing and data collection that would be part of treatment anyway non-intrusive observations and always accessing the best treatment available.

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 independent ethics review, i.e. the HDC, also within providers who have appropriate ethics standards as well and advocates for the person considered for participation.

The vast majority of non-consenting research would and I believe should be unethical, but I would like to present an argument that it is inconsistent to allow potentially uninformed treatment under the 'intention' of best interest for that patient, while simultaneously not allowing research that would inform what is actually effective treatment towards the best interest of said patients. In terms of treatment we are then relying on hypothetical best practice, the knowledge we have gained from past research that was not as ethical or in my opinion creating a double standard by observing overseas research that is not as strictly regulated.

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 typically has considerable ethical review attached to it which I would hope included complying with national standards such as HDC codes as well as laws of the land.

As I understand it the HDC's mandate is to provide guidance for people's interaction with services, not a protective body for all people with disabilities and health needs although one can see how the distinction is unclear. Research within providers is of course a serious matter than the HDC should take a strong stance on, due the complexity of issues some of which aren't mentioned such as conflicts of interest of being a provider and a researcher.

To determine how all people with consent issues should be treated within NZ is I believe outside the mandate of HDC in monitoring and protecting people's rights within services.

NZ should have a unified approach, however I believe diversity fosters innovation and more progress towards greater ethical behaviour. Not that I believe say a ministry or university should have any more leeway than the HDC code, but rather that the approach towards ethics would be diverse rather than purely legislative.
Certain rights should be enshrined in law such as doing no harm achieving some form of informed consent and so forth.

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 agree that any indication that a person is being adversely effected by the research should behoove a researcher to cease.

However this is difficult to legislate because one person's observed expression of fear, is another person's common expression, not to mention would this open up prosecution of researchers who fail to note a fearful expression despite adequate consent?

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 very limited circumstances - as I mentioned earlier in the document asking a patient if their data can be used to inform research.

Most patients would probably be unsettled to learn they had been given different treatments as part of a controlled trial

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.

As to whether is should be law or simply part of the HDC ethics process I believe that if research is possible on consenting adults then there is no need for non-consenting to be included.

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 research should only be permitted that informs the treatment of the participants and of the nature that it may improve said treatment.

For example in the adrenaline heart arrest study, there is no way such research should be used to inform say adrenaline use for intense allergic reactions.

There is a slight special pleading in the following argument however it is not irrational to suggest a person receiving dementia care should participate in research in improve dementia care if it's reasonable to think that a person might benefit from the long term increase in understanding.

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 treatment of participa
2	Removes potential risks of
3	Potential benefit to patient t
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.

For any significant study, especially medical but for case-studies, conference presentations etc I'm not sure of the feasibility and broadness of scope.

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 there needs to a more long term perspective than immediate best interest. Even the safest research has aversive quality in the sense of inconvenience, risk of data misuse (however small) however consideration needs to be given to the long term benefits of improving treatment for said person (i.e. the dementia intervention)

7.3 Please state the reasons you formed this view.

in 99% of cases a persons right to autonomy and intervention within their best interest overrides research needs.
However there are times when there is a lack of evidence base for what is in the person's best interest and cases where research may benefit the person long term, and cases where the ethical harm of providing an unstudied intervention should outweigh the ethical harm of research

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.

As far as I'm aware a welfare guardian (or a responsible clinician) can consent to a study in the best interests of a person.

I believe there is an inconsistency here, because its not so much providing respect for a person's autonomy but essentially allowing research as a by-product of trying to serve a person's best interest. By rights the most ethical thing to do would be to receive the potentially beneficial aspects of the research and then withdraw from the study as the person still does not have the autonomy to agree to their data being used.

My only thought is that it should be part of ethical approval to determine how people are recruited and thusly how the researchers will approach key decision makers, I assume only the most robust approaches are appropriate (i.e. if there is any reason the person might not participate they shouldn't)

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.

Legally the intent of a guardian is to provide proxy decisions for a person with all the considerations of the code including the persons best interest. While I agree that guardians should not be able to enroll a person into research unless in their best interests, it probably needs to be added that also a guardian may have to be considered if they request a person is not enrolled in research say for religious reasons. This should always be done in consultation not as the only decision maker.

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
- [x] Other

Additional comment.

See above

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 HDC code significant others should be considered in making decisions for a person without capacity, this does not mean ultimate veto or decision making but at least consultation

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.

Providers should be included as per HDC informed consent guidelines as a person to be consulted in regards to the person's best interests and so forth.

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.

There is a case in most ethical conundrum situations at a person or persons not directly involved in any side of their life can review the case and provide input as an independent observer

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 Provider not involved
2 EPOA or guardian
3 Family
4 Other (ethics officer)
5 Researcher

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

In general enrollment should be conservative i.e. erring towards not using participants if there are any concerns.

Final comments

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

I appreciate the opportunity to provide feedback, I understand the HDC's current stance of providing a high level of protection for vulnerable people. However I am also very passionate about the benefits of research to the same vulnerable people and feel there is an opportunity for NZ legislation and policy to show that as a country we are innovative and compassionate, not just providing a protective bubble that halters progress, but working hard to find out how to progress while still upholding people's rights, mana, and autonomy.

Please state your name

Organisation (if applicable)

CCT- Community Care Trust

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 am employed by the CCT, and this submission was approved by our CEO with review from CCT colleagues. There is no particular reason any of the material presented requires confidentiality, however in the interests of respect and consent that HDC

represents it is requested any publication is presented to myself or CCT representative for comment before being made public.

Kind regards

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 April 2017 at 8:56am | Completed on 28 April 2017 at 3:53pm

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.

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

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.

This case study appears to be based on Professor Ed Mitchell recent proposed study of RG1662 in people with Down syndrome, which was declined ethics approval (Northern A Health and Disability Ethics Committee, 2014). We note the Professor Mitchell intended to approach the Office of the Health and Disability Commissioner to push for a law change to enable the recruitment of people into studies who cannot give informed consent (Northern B Health and Disability Ethics Committee, 2014). We also note that in this case, as is likely with most clinical trials that are declined in New Zealand, the trial of RG1662 has gone ahead in other countries (Basmisanil , 2017).

As the consultation document notes some adults with Down syndrome are capable of giving informed consent (Health & Disability Commmissioner, 2017, p. 25). In larger countries, it is most likely easier to find adults with learning disabilities who are capable of consenting to clinical trials. There is therefore no real benefit for consumers from weakening Right 7(4) to allow researchers to carry out clinical trials on people with learning disabilities who cannot consent. The drug, if effective and safe, is likely to make it to market regardless. The only benefit is likely to be for researchers so they can carry out clinical trials in New Zealand, rather than overseas. Further, weakening this Right is likely to increase the risk of exploitation of people with learning disabilities. We note that just like the case study, RG1662 is linked to increased risks of suicidal thoughts as well as other side effects (Northern A Health and Disability Ethics Committee, 2014).

There is a long history of exploitation of disabled people for medical research. One grievous example was the hepatitis studies done in Willowbrook State School in New York. In these studies, children with learning disabilities were deliberately infected with the hepatitis virus without their consent. This study, which went for around 25 years, was highly detrimental to the participants. The study was justified on the grounds of benefits to others and also on the grounds that the children would acquire hepatitis anyway due to poor hygiene standards at the school. This created a self-fulfilling prophesy as the researchers then had a vested interest in ensuring hygiene standards were not raised. Like the Tuskegee experiment, which exploited another disadvantaged group African Americans, the Willowbrook experiments were of limited importance to medical breakthroughs and seemed to be more about the prestige and employment of the researchers (Rothman , 1982).

Bibliography
Basmisanil . (2017, April 21). Retrieved from Adis Insight: http://adisinsight.springer.com/drugs/800031595
Health & Disability Commmissioner. (2017). HDC Consultation Document Health and disability research involving adult participants who are unable to provide informed consent.
Northern A Health and Disability Ethics Committee. (2014). Minutes 08 April 2014.
Northern A Health and Disability Ethics Committee. (2014). Minutes 11 February 2014.
Northern B Health and Disability Ethics Committee. (2014). Minutes 1 July 2014.
Rothman , D. J. (1982). Were Tuskegee & Willowbrook 'Studies in Nature'? The Hastings Center Report, 5-7.

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.

This consultation is about adults. Adults should have the right to determine the level of involvement their families and other caregivers have in their lives. Ultimately, it will be the adult participants themselves that will undergo the trial and be exposed to the risks. Having someone else consent on your behalf to undergo a risky trial that is not part of your treatment plan is very problematic. The Code current recognises this by placing limits on substitute decision-making with adults.

Further, there is a general move in the disability community from substitute decision-making to supported decision-making where the person makes the decision with the right support (Office for Disability Issues, 2017). There is growing awareness in the disability community that some people previously thought to be unable to make an informed decision can with the right support . Article 12 of the Convention on the Rights of Persons with Disabilities requires the government to provide support to ensure people with disabilities can exercise their legal capacity.

Allowing families to consent for adults to undergo clinical trials would be a retrograde step.

Of note, both British Colombia (Representation Agreement Act) and Ireland (Assisted Decision-Making (Capacity) Act 2015) have moved towards supported decision-making.

Bibliography
Office for Disability Issues. (2017, February 08). Promoting choice and control. Retrieved from Office for Disability Issues: https://www.odi.govt.nz/whats-happening/promoting-choice-and-control/

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 for medical research.

Adults who are unable to provide informed consent should not be involved in medical research, including clinical trials. Medical research always involves risks and it is wrong for someone to have to accept these risks without their active consent. It is here, there needs to be a clear distinction between emergency medical procedures and medical research.

Yes for participatory and observational non-invasive qualitative research.

Participatory research where the researchers work with the person to tell their story or get their perspective may be allowed under certain circumstances. Done right, this time of research can be empowering for participants.

Observational non-invasive qualitative research is less empowering, but it is sometimes the only way to tell the story of otherwise invisible 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.

Participatory non-invasive qualitative research should only be allowed if the person participating has expressed that it is their will and preference, under a supported decision-making process, to be involved in the research. A Health and Disability Ethics Committee should also approve this research

Observational non-invasive qualitative research should only be allowed if approved by a Health and Disability Ethics Committee. The Committee should be satisfied that the primary purpose of the research is to push for improvements in the participants' wellbeing (by highlighting current issues). The Committee should also be satisfied that the research respects participants' rights under the Convention on the Rights of Persons with Disabilities, including the participants' right to inherent dignity. If any participant expresses that they do not want to be part of the research (including through supported decision-making processes), they should have their wishes respected and be excluded from the research.

In either case, no identifiable information about a person should be published unless they have given (and continue to give) their active informed consent.

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 would make the current situation clearer. In addition, there is confusion about the differences between evaluations, audits and research. The code should be clearer about what it applies to.

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 seems self-evident that any researcher should stop if a participant indicates they no longer want to be part of the research. No researcher should continue the research in this situation, regardless of whether the person can formally give informed consent. Suggesting otherwise risks a return to past mistakes, where researchers would continue with deeply unethical research against the wishes of participants under the dubious guise of the greater good.

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 or retrospective consent is not genuine because the intervention has taken place. If the person declines delayed consent, there is typically no way to reverse what has already happened.

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 medical research is banned for people who cannot consent, making this a legal requirement is probably unnecessary. If medical research is allowed for people who cannot consent, then this is an important safeguard and should be a legal requirement.

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 (unless it is participatory non-invasive qualitative research and they have expressed their preference to be involved through a supported decision-making process).

This type of utilitarian logic is behind some of the most unethical research conducted, including the Willowbrook hepatitis studies. Vulnerable people who cannot give consent should not be used as test subjects for research to benefit others. The risks of exploitation are far too great.

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 important 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.

Yes (although for participatory non-invasive qualitative research instead the person could express a preference to be involved through a supported decision-making process). The best interests tests must also not precede nor result in less focus on supporting an individual in making decisions that reflect their true wills and preferences, not a third party's interpretation of them.

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.

People who cannot legally consent are vulnerable to exploitation in medical research and there is a history of exploitation. The Health and Disability Commissioner needs to hold fast to the existing rights that are guaranteed in the code. No medical advance is worth the price of exploiting a vulnerable population.

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.

We are happy to provide more information and answer any questions about this response:

Please state your name

Organisation (if applicable)

CCS Disability Action

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 28 April 2017 at 3:35pm | Completed on 28 April 2017 at 4:30pm

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.

Low risk and could be helpful to 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.

Low risk and might be helpful to others

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

I would have thought that my consent could have been obtained prior to this operation and that would be my preference and expectation

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.

My instinct is that increased interaction is the right thing to do and dementia is such a prevalant condition I would want to help.

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 sounds too high risk to me and selfishly I would rather that others were the trial participants

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

Impractical. I wouldn't wear a bracelet on the offchance that I had a cardiac event and that someone then paused their protocol (adrenalin) to check to find it and read it. We need some sort of register for opt outs.

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 high risk

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 really concerned that caregivers could make a decision that is not in the best interests of the individual. Caregivers could be swayed by, or confused by, quite complex research participant information. This research is too high risk.

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 it is the only way that important research can be conducted and if the risk of harm to the individual (physical and emotional harm) is very low.

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 potential benefit of the reserach must be significant, the research must have some direct connection with the person such as the same health or disability condition that the person has, the potential risk to the person must be negligible and this must include the potential emotional harm of inclusion to that individual, not to the general public. In particular for an individual with autism, would the research involved physical experiences which are unpleasant for that individual such as unfamiliar or noisy/busy environments, application of bandaids, injections, or unpleasant odours. Any of these may be overwhelming. the person being consulted on behalf of the research participant must be able to understand the research information and ask questions and know the research participant and how they would be likely to experience participation. In addition an independent advocate experienced with the research sector but consumer aligned should also consider whether participation is appropriate.

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.

Research such as observational research can be very intrusive. For example in a group residential home there would commonly be 4 or 5 men with autism and anywhere up to 4 caregivers in a house with one living area. To add a researcher to that mix could be detrimental to the residents.

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

Refusal must be subjectively asssessed and for some participants vocalisation or behaviours may be the only means of 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.

Informed consent is a cornerstone of NZ's health law. If the person is unable to comprehend and evaluate information prior to the research then consent is not possible. I can't see the point of trying to do this after the event either. All that can happen is that the patient is informed that they were enrolled and why.

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 is an essential protection to ensure that the vulnerable are not used 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.

But only if this is the only way of conducting the research and it has likelihood of value to that group - either by showing that an existing treatment or practice or theory is of negligible benefit or to show possible benefit and justify further 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	be permitted only if it may b
2	be intended to provide kn
3	be intended to contribute
4	be connected to the impairi
5	the individuals must have p
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 a very vulnerable group of people and independent ethical overview is an important part of the checks and balances

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 agree with the criteria set out in the Scottish legislation except that I would prefer an independent advocate instead of a health professional and the same wording as is used in the Code instead of "nearest relative".

7.3 Please state the reasons you formed this view.

This seems to be the tightest protection but allowing for more research than is possible at present.

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.

If a welfare guardian is available then only they should be able to consent, but family should still be able to veto unless this is not in the best interests of the consumer

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.

And independent advocate

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
- [ ] 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 guardian
2 Family/whānau
3 Independent advocate
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.

Thanks for taking on this very important consultation.

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 27 April 2017 at 2:48pm | Completed on 28 April 2017 at 4:34pm

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.

As I am unable to give informed consent and the research would not be of any benefit to me, I should not be enrolled in this or any research study or clinical trial.

It is obvious from having attended meetings of the ethics committees that the HDECs no longer have as a major priority the protection of research subjects, both those who are able to give fully informed consent and those who are unable to provide informed consent.

Currently in New Zealand there is a great deal of research being undertaken on a wide range of vulnerable people who are not able consent to taking part and who are being used as guinea pigs for the research industry. Until a few years ago I had assumed that the Cartwright Inquiry and the Report had dealt with this issue and that it would no longer be possible for anyone to be enrolled in research trials without their written consent.

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 I am unable to give informed consent and the research would not be of any benefit to me, I should not be enrolled in this or any research study or clinical trial.

As previously noted it is obvious from my having attended meetings of the ethics committees that the HDECs no longer have as a major priority the protection of research subjects, both those who are able to give fully informed consent and those who are unable to provide informed consent. This means that the HDC must act with some urgency to provide the protection that research subjects in New Zealand urgently need.

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

"Delayed consent" is unethical and in contravention of New Zealand's obligations under the Helsinki Declaration as well as other international obligations to vulnerable populations.

It is also an irrational concept in that truly informed consent cannot be regarded as being able to be freely given or withdrawn once a research subject has been enrolled without their permission a in research study. Once the patient has been given a drug or had a medical procedure provided as part of a clinical trial such actions cannot be reversed. This puts patients in an invidious position as simply not including their data is not enough to undo the actions they have been subjected to without their expressed 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.

Vulnerable persons need to be protected from being enrolled in clinical trials or any research studies without their consent. There should be no exceptions made.

I have listened to researchers justifying their including patients who do not have the capacity to give informed consent to taking part in their particular research study, and given that I recognise all but one of the case studies in the HDC's consultation document, I have formed the view that a specialised panel or a fifth ethics committee is needed that has as its core function the protection of vulnerable groups of people such as those with dementia, those in prison or detained in youth facilities (yes, they, too, are currently being used as research subjects), those with Down syndrome,
etc. I have also become aware that family members of those who are unable to consent to taking part in research studies are also vulnerable when placed in the position of being asked to consent to their relative being enrolled in a research study. Some family members spoke out about this practice following the front page article about enrolling unconscious patients in clinical trials that appeared in the NZ Herald three years ago.

Until the legal situation regarding this unacceptable practice is resolved and regulations are introduced that provide a much needed form of protection for such patients and their families, the practice of enrolling people in research without their consent must cease.

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.

As noted already, 7 - 8 years of regularly attending ethics committee meetings have led me to conclude that there is a urgent need to protect vulnerable persons from being enrolled in clinical trials or any research studies without their consent. There should be no exceptions made.

Until the legal situation regarding this unacceptable practice is resolved and regulations are introduced that provide a much needed form of protection for such patients and their families, the practice of enrolling people in research without their consent must cease.

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

Experience has shown that "opt out" processes often do not work in the way intended. It would be extremely difficult if not impossible to raise awareness through a public information campaign about the need to wear a "NO STUDY" bracelet if you do not want to take part in a clinical trial like this. It could not be assumed that a patient not wearing a "NO STUDY" bracelet was not wearing one because she or he was aware of this research study and was consenting to take part.

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 witnessed the unfolding drama around this particular research study with great interest. It was another wake-up call to the fact that there was an urgent need to protect the well-being of vulnerable persons and their families. The discussions that took place also clearly demonstrated that ethics committees could no longer be trusted to place the interests of research subjects above those of the researchers.

It also highlighted the need to set the benefit threshold very high and the risk threshold very low for all research subjects, not just for vulnerable populations of people such as those unable to consent to taking part in 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.

As already noted, I have become aware that family/whanau/caregivers are also vulnerable when faced with being asked to give consent for their relative to be enrolled in one or more clinical trials. It is not unusual for a relative to be asked to consent to their family member being enrolled in more than one!

Researchers get very enthusiastic about the benefits of their particular area of research, and they are all at risk of overselling the benefits and downplaying the risks. I have witnessed this during attending ethics committee meetings.

I am especially concerned at the increasing number of "me too" clinical trials that come before the ethics committees. These are drug trials in which there is absolutely no benefit to the research subject or future patients, and the only benefit is to the particular drug company who wants to make money out of a drug they want to bring on to the market that is almost identical to a drug or drugs that other drug companies are manufacturing and making big profits from.

Since the restructuring of the ethics committees in 2012 New Zealand is now seen as a soft touch by the pharmaceutical company for Phase 1 or "first in man" drug trials. This is often commented upon by ethics committee members. However, these drug trials are still given ethics 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.

Until New Zealand has ethics committees that are unpinned by statutory regulations, and until ethics committees have as their main priority the protection of research subjects, rather than the interests of the researchers and the need to meet the ethics committee time clock, and until other provisions, such as an expert panel or specialised ethics committee similar to the way ECART was established are introduced, research should not be undertaken on adults who are unable to provide 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.

Very strong safeguards are needed to protect groups of vulnerable people who for whatever reason are unable to provide informed consent to taking part in research trials.

The current law is not being adhered to, and nonconsensual research is being undertaken on a daily basis in New Zealand. The "best interests" threshold in Right 7(4) of the Code of Consumers' Rights is not protecting vulnerable groups of patients in the way it was designed to. This untenable and unethical situation must be rectified as soon as possible. It is outrageous that the HDC has taken years to address the issue.

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 believe that a detailed and legally binding set of regulations is needed to provide an effective safeguard for the rights of all research subjects in New Zealand.

There should also no research conducted on patients who are unable to consent to being enrolled in clinical trials in which there is no benefit to the patient.

The Code of Consumers' Rights and the current system of ethics committees cannot be relied upon to put the protection of research subjects above the interests of researchers, the pharmaceutical industry, and the need to meet the deadline of the ethics committee clock.

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

In my opinion the rights of those with disabilities need to be given a great deal more protection than they currently are. The autonomy of incapacitated persons must be respected which requires that they be included in the informed consent process as far as possible.

Supported decision-making as outlined in the Convention on the Rights of Persons with Disabilites, and also as described in

Right 7(3) of the Code of Consumers' Rights should be mandatory requirements.

Any sign of discomfort, objection, or an unwillingness to continue with any procedure that is being undertaken as part of a clinical trial should be acknowledged and the person should be withdrawn from the trial.

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.

As already noted "delayed" or "retrospective" consent is not an acceptable justification to the inclusion of incapacitated person in clinical trials. It is also unethical.

The research subject may never regain the capacity to give consent, and even if they do, there is no way of reversing the actions that have been undertaken during the time they were enrolled as research subjects.

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.

Legislation is needed that stipulates that incapacitated persons can only be included when it is can be demonstrated that competent subjects cannot be used. This would apply once the provisions already outlined in my submission have been implemented.

It also needs to be pointed out that this is the situation that features in all of the overseas models, including the European Regulation 2015 31.1(e), the UK's Mental Capacity Act 31(4), and Scotland's Adults with Incapacity Scotland Act (AISA) 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.

In my opinion it is unacceptable and unethical to use incapacitated persons in research that does not result in any personal benefit to these individuals.

As already noted strict legal safeguards would need to be enacted if it consideration is given to making non-therapeutic research lawful in some circumstances.

I am concerned about the possibility of regulatory creep for vulnerable groups of patients who are enrolled in research studies which do not benefit 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	No or very minimal risk
2	No foreseeable burden
3	Informed consent of legal re
4	No indication of unwillingne
5	Ethics Committee approval
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 already noted all overseas models require this essential condition. Incapacitated persons who are unable to weigh the potential risks against the possible benefits and decide for themselves whether they wish to participate need to be protected by strict safeguards enshrined in legislation.

The HDECs and the Code of Consumers' Rights currently do 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?

The criteria must include the need to demonstrate that there is evidence that taking part in the research study will produce a real and direct benefit for the incapacitated person.

The inclusion benefit - the research subject will receive better care and monitoring if they take part - should never be used as a benefit.

As already noted, the benefit threshold should be set very high and the risk threshold must be minimal or no risk.

7.3 Please state the reasons you formed this view.

As noted already, 7 - 8 years of regularly attending ethics committee meetings have led me to conclude that there is a urgent need to protect vulnerable persons from being enrolled in clinical trials or any research studies without their consent.

Until the legal situation regarding this unacceptable practice is resolved and regulations are introduced that provide the much needed forms of protection for such patients and their families, the practice of enrolling people in research without their consent must cease.

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.

As already noted the currently situation in New Zealand does not provide adequate protection of incapacitated persons who are being enrolled in research without their consent.

One of a number of options in addition to those already mentioned in this submission, is to introduce the legal ability for a close family member or legal representative to give consent to the patient's inclusion in a research study that offers benefit to the incapacitated person.

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.

Incapacitated persons who are unable to provide consent should not be enrolled in clinical trials unless participating in the trial offers a clear and evidence-based benefit to the person.

As already noted once legislative changes have been made to the current situation, a legal representative could possibly be asked to give consent if they were an Enduring Power of Attorney or a welfare guardian.

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.

As previously noted in this submission, a legal representative or decision-maker should be an EPOA or a welfare guardian. I expect that the EPOA would probably be a close family member.

Scotland's AISA provision states that "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."

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?
- [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.

Should this consultation not result in the important legislative protections currently needed for incapacitated persons, and the incapacitated person has no legally appointed EPOA, then a truly independent provider who is not involved in the research could be involved in decision-making.

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 guardian
2 Family/whanau
3 Close friend
4 Consumer's GP
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.

This consultation process has been woefully inadequate in that no public meetings were held to discuss the issues; the use of case studies and asking for personal decisions is extremely manipulative as it presents a misleading simplification of what is involved in agreeing to take part in research; and the effort of trying to complete the consultation document online while copying and pasting all responses into a word document made it time-consuming and not in the least bit user-friendly. Fortunately I had been warned by others that I would not be able to save a copy of my submission once I had completed it which meant it was essential to create a separate copy in a Word document as I went.

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 28 April 2017 at 4:08pm | Completed on 28 April 2017 at 5:14pm

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

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.

IHC's view is that adults with intellectually disability should have equal access to participate, and to decide whether to participate, in research. This is consistent with the rights of disabled people under Article 12 of the United Nations Convention on the Rights of People with Disability (UNCRPD).

Not allowing research to proceed unless the participant is able to provide informed consent unnecessarily limits opportunities to learn about the lives of adults with intellectually disability and gather the information needed for robust, evidence based policy and practice.
For people with intellectual disability this question, and others in the consultation document, raise issues to do with informed consent and supported and substitute decision-making. We submit that the consultation document does not adequately recognise the ability to express will and preference, the right to supported decision-making, and the safeguards set out under the UNCRPD. There appears to be a presumption (as illustrated by New Zealand's legal and ethical framework, Figure 1 on page 10 of the consultation document) that if someone lacks the capacity to consent they will not be involved in decision-making about participating in research. There is recognition at the top of Figure 1 of the presumption of competence and that the consumer should be provided with support and help to be able to make and communicate a decision. However if someone is deemed unable to consent it is unclear how their right to participate in decision-making is given effect to.
IHC believes that before there are any changes to the Code of Health and Disability Service Consumers' Rights (the Code) a more thorough exploration of these issues is required. This needs to be linked with the current collaborative work being facilitated by the Office of Disability Issues on support for the exercise of legal capacity.

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

Fundamental principles of research such as providing sufficient information in formats that are able to be understood, enabling fully informed decisions about participation, and participants being able to withdraw at any time, apply to all participants including those with intellectual disability. Blanket provisions or criteria that include or exclude people with intellectual disability without taking into account their particular individual circumstances and the type of research being undertaken should be avoided.

The distinctions made in the consultation document between interventional and observational research are important ones. In addition, processes for considering potential restrictions on research participation need to distinguish between low risk/low burden research and more intrusive high risk/high burden research.

Any criteria and restrictions applied should be consistent with and promote the UNCRPD , particularly the following principles:
- Access to support to enable consent and participation in decision-making
- Supports and safeguards to ensure that the rights, will and preference are 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

To do otherwise would be unethical and inconsistent with the UNCRPD. As with all research participants, people with intellectual disability must be able to dissent or refuse to participate and to decide to withdraw from research at any stage and be able to give effect to that decision. They may need support to do this. Others who know the person, their preferences and how they express those preferences, can play an important role in interpreting and giving voice to the persons will and preference. This need not be a welfare guardian and highlights issues to do with the distinction between substitute and supported decision-making that we raise throughout this submission.

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.

IHC does not support delayed or retrospective consent for the same reasons that it is currently not allowed. The research will have already been done once consent is obtained or withdrawn.

Also, the concept does not readily apply to people with intellectual disability and reflects the problems raised by the consultation

document not adequately identifying or analysing the reasons for incapacity. Two problems arise:
(i) It is unlikely that once deemed incompetent people with intellectually disability will be regarded as competent in the future.
(ii) It reinforces outdated assumptions that just because people with intellectual disability may need help to make some decisions they are not competent to make any decisions.

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 question underscores the confusion created by conflating incompetence due to being in a coma and being deemed incompetent to consent due to intellectual disability.

For people with an intellectual disability the answer will depend on their circumstances and the nature of the research. A blanket legal requirement risks excluding people with intellectual disability from participating in any research, including population wide research. As noted above, this would restrict opportunities to learn about their lives. We have particular concerns that having a legal requirement would mean people with more severe impairments would be more likely to be excluded.

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.

IHC believes that there may be times when research on person with intellectual disability who is deemed incompetent to consent should be permitted even if it is unclear whether the research will benefit the individual involved. Like others, people with intellectual disability will have a wide range of motivations for participating or not participating in research. There is no need to limit their participation in research to research that benefits them individually and to do so prevents them from contributing.

We question why it is thought that there needs to be criteria about the group of people intended to benefit from the research. There are not criteria for people deemed competent.

Ethics committees are best placed to decide when such research should proceed as decisions need to be made on a case by case basis.

It will be critical that ethics committees and decision-makers are well informed about and have a good understanding of best practice research methodology with people with intellectual disability.

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 is not possible to answer this question without greater consideration of the underlying principles and wider issues for people with intellectual disability that we have raised throughout this submission.

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?

Reliance on the concept of "best interests" is problematic. The United Nations Committee on the Rights of Persons with Disability have identified the use of "best interests" as a barrier to moving from substitute to supported decision making. They have recommended the use of "will and preference" instead of "best interests". We note the Committee on the Rights of Persons with Disabilities recommended in 2014 that New Zealand take immediate steps be taken to revise relevant laws and replace substituted decision-making with supported decision-making (see CRPD/C/NZL/CO/1, paragraph 22).

The current test does not strike the appropriate balance between protecting the rights of consumers who are unable to give consent and allowing the research to proceed. Neither does it strike the right balance between the rights of people with intellectual disability to the supports and safeguards that ensure decisions are made in a way that respects their will and preference.

Striking the right balance is especially critical for those people who are reliant on others to interpret and represent their preferences and decisions.

It is important to have a legal test that reflects and enables the right balance to be struck. However, how that law is implemented will be what makes the difference. A legal change on its own is insufficient to change practice.

The current threshold for participation is too high and fails to recognise the many motivations people with intellectual disability may have to participate. IHC would support a wider basis for participation that includes a more nuanced understanding of personal agency and supported decision making.

Criteria/tests to assess the advantage and disadvantage to participants need to respect the rights, will and preferences of person and be appropriate, proportional and tailored to the person's circumstances. (See Article 12 UNCRPD)

The definition and application of best interests needs to be looked at to ensure consistency across the different areas in which it is applied. For example its application under the Code should be consistent with the PPPR Act. Throughout this submission there are wider issues raised about decision-making affecting those with intellectual disability. Again we suggest that the relationship between the best interests test and "will and preference" needs to be better explored and articulated to ensure consistency between law, policy, practice and attitudes. As an example, resources developed by and past and current workshops and webinars run by IHC's Advocacy team provide practical applications of supporting decision making and contribute to building community capacity.

7.3 Please state the reasons you formed this view.

Please see our response to 7.2.

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.

This question also begs other, wider questions to do with substitute and supported decision making. In cases where there is substituted decision-making, how will the will and preference of the prospective participant be respected? What will be done to ensure decisions to include/exclude are in the best interests (see comments above on best interests)? Where appropriate will there be mechanisms for review in accordance with Article 12 of the UNCRPD? These issues need to be worked through before the question of who decides can be answered.

Whoever the ultimate decision-maker is, the person with intellectual disability should be part of the decision-making and has a right to support to enable their participation. What decision is made will depend on the circumstances and needs to be decided on a case by case basis. Having criteria risks being too prescriptive rather than enabling.

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.

We were unable to complete this section because of the space limit. We will send our overarching comments and key point by email.

Any problems please contact

Please state your name

Organisation (if applicable)

IHC

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 29 April 2017 at 8:26pm | Completed on 29 April 2017 at 8:41pm

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.

See Answers below for Cases B, C and E

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 am unconscious due to having neurosurgery, this implies that I am not informed about the nature of the research and what exactly I would be participating in. There is no way that is a situation that I would be comfortable with. Informed consent is a cornerstone of research ethics. In any research a participant has to be informed about the nature of the research and then willing to participate. There are certain situations where this is not possible, such as when someone is unconscious. The Code of Health and Disability Services Consumers' Rights states that this is a requirement and includes that any risks and side effects must be communicated to a participant. It also states that it must be communicated in a manner that allows the consumer to understand it. This would certainly not be possible if I were unconscious due to having neurosurgery.

The code also states that the research can include a person that is unable to consent if the researcher decides that it would be in the person's best interests to be a participant in the study. I can not see how participating in this study would benefit me as a person having neurosurgery. As mentioned in the consultation document, there is currently no evidence that either of the treatments are more effective or safer than the other. If this is the case, then there is no possible benefit of me (a neurosurgery 'consumer') receiving a better treatment, in the eyes of the current evidence.

The consultation document states that there is currently no evidence that either of the treatments are more effective or safer than the other. There is little scientific merit to this study. If there is currently no evidence of a difference then it appears to me that this study is being based off of a hunch that there may be difference between the two treatments.

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

Delayed consent is not a legal form of consent for good reason. If a person is unable to give consent because they are unconscious due to having neurosurgery, then they should not be included in a study until they are able to give consent. Consent should not be assumed when the question hasn't been asked. If consent is yet to be sought, then the default position should be that the person has not consented.

If the researcher decides that participating in this research is in the best interests of a person and data is collected before they are able to give consent, the data should be added into the study if they say yes, rather than it being removed if they say no. The default position should not be that a person who has had their data collected without consent will agree to having the data used, but rather that they will not agree to it.

The practice of assuming consent will be given before the consent has been sought is coercive. The patient may not want to say they don't want to participate for fear of being seen as someone that is causing trouble for the researcher, who may also be their doctor. This exposes the unequal power dynamics in the researcher-participant relationship, an issue which is only augmented due to the potential doctor-patient power dynamic.

The consent process could be made worse depending on when the consent is sought. How much time will elapse between the accident, the intervention, and the seeking of consent may increase the level of coercion involved. If consent is sought too early after the intervention (i.e. very soon after the patient wakes up) then they may feel pressured by the situation and like they have to respond right away. This would lead to them not having enough time to properly consider all of the information and therefore not make a fully informed decision regarding their consent. If the delay is too long (i.e. after an amount of time that has allowed the patient to see that the treatment has worked) then there is the possibility of the patient feeling obliged to give their consent as a thank you to the doctor that treated them.

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.

Multiple problematic aspects exist within Case Study C that have contributed to my decision not to participate in this research if I was a person with dementia and unable to provide consent. The case lacks proper justification, scientific merit is never established and flaws exist within the basic method. Fundamental ethical principles such as beneficence, equipoise and potential coercion stemming from conflicts of interest are ignored. The one page of information provided does not provide enough information for individuals to make a fully informed decision, and alternative explanations for potential results and how this would be managed are not discussed.

Nowhere in the information provided is justification for the study established. While Dr. C "thinks conventional care may be neglecting consumers' psychosocial needs," this is simply the doctor's personal opinion. It seems that Dr C has a theory that he/she would like to test out, even though no substantial justification to do this research has been provided. The use of patients with severe dementia in this study also lacks justification, as no reasoning is given why patients in the earlier, less severe stages of dementia or other groups who are less vulnerable could not be used instead.

Thorough consideration has not been given to the proposed method of the study. The study advises that patients will be split into two groups who receive different types of care: group one receiving the ordinary conventional care, and group two receiving interactive care. While both these groups are obviously necessary to test the success of an interactive care program, another group has been overlooked: a control group who are not aware they are being studied.

The proposed study fails to acknowledge and incorporate many central ethical principles into its design, such as beneficence, equipoise, coercion and conflicts of interest.

- The ethical principle of beneficence states that research should be of benefit, and not of harm to any subjects involved in it. The proposed study clearly outlines, "it is not known whether the research would be in participants' best interests," indicating the possibility that there will be no benefit to the patients receiving the interactive care at all.
- Non-maleficence is another ethical principle that relates to the potential risks of participating in research. Non-maleficence states that any potential harm must be minimised, however in this case it is disclosed that there is an emotional and psychological risk to participants, as they "may find the additional contact distressing." The lack of certain benefit and the confidence in likely harm in this study goes against standards of beneficence and nonmaleficence, and does not put the patient, and their wellbeing at the forefront of this research.
- Clinical equipoise states that if a new treatment is being tested, a true null hypothesis must exist, meaning that neither the new treatment nor the one it is being tested against are known to be better. The suggestion in the third paragraph that the "additional assessments could benefit the participants," attempts to preempt equipoise by focussing on the potential positive outcome of the new interactive care program. Concentrating on possible benefit of the interactive care treatment and not equally acknowledging the possible benefit of the existing trial may lead readers of the proposed study to therefore believe that the interactive care treatment is better, when clinical equipoise states that neither can be proven more effective.

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.

no answer given

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.

The concept of beneficence seems to have been neglected in this case study in that the participants are put at risk in several key ways.

- The drug that will be tested is said to increase suicidal thoughts for some who use it. This has the potential to be problematic for the participant as it could have very negative effects on their well-being, to the point of being potentially life-threatening.
- As the double-blind study involves participants who may not be able to give consent because of the degree of their Down syndrome, it implies that these particular participants would have particularly severe forms of the disability.

It could be hard to manage suicidal thoughts in someone with severe Down syndrome as often communication is an issue, meaning they may have no way of communicating how they are feeling, or potentially could, but simply choose not to. They would also potentially lack the mental capability to process these sorts of thoughts. This would also be problematic as the study is structured as randomised and double-blind, meaning neither the researcher nor the caregivers of the participant would know whether the participant had received the drug or not. This would mean they would not know whether they should be concerned about these side effects and attempt to cater for the potential of them in some way.

The case study also suggests no attempt to provide support programmes for those who may have these thoughts and also implies there may be other side-effects which have not yet been discovered. If some of the known side effects are suicidal thoughts, then some of the potential undiscovered side effects may be of an equal level of emotional damage, and therefore very damaging to the participant. The case study also suggests that participants would be required to undergo regular six-hour assessment visits to check their progress. In participants who are unable to give consent, which again are presumably those with fairly severe forms of Down syndrome, six hour assessments could be very stressful. Six hours is a long time, and to be constantly assessed for that time could be exhausting for the participant.

The case study also mentions that the participant would not have access to the drug once the trial had ended, meaning any improvements in cognitive function would be temporary. This change in mental functioning could be traumatic for someone with severe Down syndrome, as their ability to understand why this change is happening and their subsequent ability to cope with it could potentially be impaired.

When we consider this in relation to the potential of suicidal thoughts, the fluctuations in mood after finishing the trial drug could also be stressful for the participant. As they are potentially unable to communicate this stress, this could become a very emotionally stressful experience for them. It seems the negative effects on the participant in this case study greatly outweigh the benefits which would be gained from trialling this drug.

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 proposed consultation process does not give the participant sufficient protection. The key issue with the proposed idea is that Down syndrome exists across a spectrum, and each individual with the disability is affected by it to a degree which is unique to that individual. Some individuals with Down syndrome would be capable of giving consent, and as mentioned in the case study they should be able to give consent in accordance with ordinary consent principles. However those who are deemed unable to consent prove problematic as there is a problem of definition – who is deciding who is or isn't capable of providing consent, and what guidelines are they basing this decision off? It is unclear where the boundaries of capability of consent are being drawn, and that the person who is making this decision is acting in the best interest of the participant. If the person making that decision is a member of the participant's family/whanau/caregiver, there is no guarantee that they are making that decision in the best interest of the participant. There is also a lack in clarity in the potential side effects of the drug, meaning that even if the participant's family/whanau/caregiver are consulted about the experiment there is no way for them to be fully prepared for the potential outcomes of the experiment as the experimenter simply does not know the full extent of the potential side effects. A lack of knowledge of this could place them in a situation where they are unable to deal with these unknown side effects, which could be damaging for both the participant and their family/whanau/caregiver. Even if the family/whanau/caregiver are able to be informed on the nature of the experiment to the point of being able to give their consent, it seems difficult to give them a full set of information when even the researcher is dealing with a certain level of unknown information.

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.

There was an unacknowledged irony throughout the document relating to the word 'consumer' in reference to those who are requiring medical help, but are in some way unable to easily give informed consent. The word 'consumer' is used frequently throughout the HDC document, but proves difficult as it implies that the individuals have some level of free choice in their use of certain medical aid or medication, which often they do not. With particular reference to the individuals mentioned in the HDC case studies, their autonomy is often greatly diminished by their medical condition. The point of the HDC document seems to be how to manage those who are not in a position to actively give consent, so to then call these people consumers and imply a sense of active choice in their use of medical care seems contradictory. Those who are unconscious, or otherwise mentally impaired, are in no way able to make an active choice to need some certain medical care, but labelling them as consumers implies that they are and could in some way influence the reader to also take on this belief.

Please state your name

pplicable)

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 April 2017 at 5:20pm | Completed on 30 April 2017 at 6:53pm

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.

It would honor my altruistic desire to contribute to improved health care.
Also, of course, it is no risk to me.
To not allow this sort of research, because it currently does not meet the requirements of the code, disrespects my (and most people's) desire to facilitate such research, and it is a tragic barrier to progress.

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 would honor my altruistic desire to contribute to improved health care.
However, I would like reassurance that the current acceptance of both options as being both OK and equal, is correct. I would like that reassurance from a review by an ethics committee.
To not allow this sort of research, because it currently does not meet the requirements of the code, disrespects my (and most people's) desire to facilitate such research, and it is a tragic barrier to progress.

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

Delayed consent does allow the patient to withdraw from further involvement - use of their data and, potentially, followup commitments. Of course, all participants should be able to withdraw from any research for which they have already consented. However, I don't consider this to be a 'delayed consent' because a presumed consent has already occurred to involve them in the research. This is a withdrawal or confirmation of consent as circumstances (competence) have changed. My point is that 'delayed consent' is not a substitute for getting the initial presumption of consent right.

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 would honor my altruistic desire to contribute to improved health care.
However, there is a potential harm associated with this research - distress for the participant. This would be apparent as the

research progresses. I would want reassurance, verified by a review by an ethics committee, that any such harms would be monitored and, if noted, this would result in termination, (or at least, appropriate modification), of my involvement.

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 honor my altruistic desire to contribute to improved health care.
However, I would want reassurance, from an ethics committee review, that the current knowledge does, indeed, say that the accepted 'best practice' (adrenaline) might not be the right thing to do and that there is genuine 'equipoise' in the argument for and against adrenaline. If so, randomising me to either arm of the study gives me equal chance or benefit or harm. I would be happy with that.

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

It isn't really a pragmatic alternative to a good 'presumed consent' process, as most people who ultimately are eligible for the study will not have responded. For those who do 'opt out' it is important that their refusal is honored - so useful for those who do respond in this way, but most will not have opted in or out when they become eligible.
However, the process of communication and giving the option, is very useful - both to communicate this specific study but also to raise awareness of these issues in general.

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 honor my altruistic desire to contribute to improved health care.
However, this is a study that would cause me more concern as a potential participant. In addition to the intrinsic benefits and harms of the study, if I improved but then lost access to the drugs after the study, I would consider that an additional harm (for myself and my family).
Furthermore, this is not an acute/urgent condition I have, nor is there an urgent need to find a useful treatment. Furthermore, this context is likely to be associated with family/whanau/caregivers who are close and their input (while not necessarily legally definitive) is important. Elsewhere in right 7.4 of the Code, it instructs the provider to: take into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider. So, I would expect that to occur even when the 'best interests' requirement is modified.

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.

Of course, the devil is in the detail of the consultation, but my comments above apply:
..this context is likely to be associated with family/whanau/caregivers who are close and their input (while not necessarily legally definitive) is important. Elsewhere in right 7.4 of the Code, it instructs the provider to: take into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider. So, I would expect that to occur even when the 'best interests' requirement is modified.

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 would honor the altruistic desire to contribute to improvements in health care.
Currently right 7.4 of the code, in its requirement for 'best interests' - while laudable in its intent to protect the individual, thwarts good and useful research which the individual would want to contribute to. In that respect, it can be an 'unethical' barrier to doing the right thing.

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 clinical arena we deliver care to patients unable to consent, and frequently to those who are expressing a desire not to be treated, if there is good reason to believe their true autonomous wish (if competent), is to be treated. This is a very common ethical deliberation in emergency medicine in particular, and right 7.4 of the code is consistent with, and permissive of this approach.
For involvement in research the same approach is appropriate - do we have good reason to believe that, if this patient was well informed, competent and free from coercive influences, would they consent to participation in the research?
If there is good reason to believe that they would consent then respecting their autonomy mandates we include them. To not include them in this context, because of a default thinking that not including them is protecting them is, in fact, a disrespect for their true autonomous wishes.
However, consideration or risks, benefits, the patient's view of these (from them or from those close to them), and careful review by an ethics committee, is necessary to ensure we get this presumption of consent right.

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 allow the patient to withdraw from further involvement - use of their data and, potentially, followup commitments. Of course, all participants should be able to withdraw from any research for which they have already consented. However, I don't consider this to be a 'delayed consent' because a presumed consent has already occurred to involve them in the research. This is a withdrawal or confirmation of consent as circumstances (competence) have changed. My point is that 'delayed consent' is not a substitute for getting the initial presumption of consent right.

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 the research is just as good without including incompetent persons, and incompetent patients are not disadvantaged as a consequence (by the new knowledge not able to be applied to them), then of course the research should be confined to those who can consent competently. However, the argument is that excluding incompetent patients because of an over zealous desire to protect them might, in fact, be disadvantaging them in failing to respect their true autonomous wishes. So, yes is my answer to the question, but only if there is a genuine equivalence in the value of the research to all.

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 earlier answers.

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	I don't understand this ques
2	
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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.

As discussed in previous questions.

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 previously stated: In the clinical arena we deliver care to patients unable to consent, and frequently to those who are expressing a desire not to be treated, if there is good reason to believe their true autonomous wish (if competent), is to be treated. This is a very common ethical deliberation in emergency medicine in particular, and right 7.4 of the code is consistent with, and permissive of this approach.
For involvement in research the same approach is appropriate - do we have good reason to believe that, if this patient was well informed, competent and free from coercive influences, would they consent to participation in the research?
If there is good reason to believe that they would consent then respecting their autonomy mandates we include them. To not include them in this context, because of a default thinking that not including them is protecting them is, in fact, a disrespect for their true autonomous wishes.
However, consideration or risks, benefits, the patient's view of these (from them or from those close to them), and careful review by an ethics committee, is necessary to ensure we get this presumption of consent right.

7.3 Please state the reasons you formed this view.

As above.

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.

Apologies, I'm not sure I can answer this without further explanation of what the questions are seeking.

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
- [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.***

- [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.

- [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.

Depends on who the person is.

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 haven't ranked decision makers. I consider decisions would be collaborative, with ethics committee confirmation. Obviously the patient, and those close to them, would usually have the top positions in the ranking, but it is dependent on the nature of the research, the nature of the competence, and the relationship of the family/whanau

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 April 2017 at 7:50pm | Completed on 30 April 2017 at 7:55pm

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

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.

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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.

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.

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2
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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.

NZACRes would like to express support for this important initiative. This review will contribute to ensuring NZ has a robust research environment.

Please state your name

Organisation (if applicable)

NZACRes -

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 April 2017 at 7:42pm | Completed on 30 April 2017 at 7:55pm

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

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

To save their life.

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.

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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.

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.***

- [ ] 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?
- [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 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?
- [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 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 welfare guardian
2 provider not involved in res
3 family
4 researchers
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 30 March 2017 at 9:09am | Completed on 30 April 2017 at 8:20pm

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.

This is an observational study. Therefore no additional interventions are being performed however perhaps more attention than usual would now be made to taking and recording of my observations. Paying closer attention to my observations has the potential to aid me directly as a current patient in addition to providing possible benefits to other future patients based on the results of the observations.

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 the researchers have gained ethics approval to conduct this study they will have had to show a current state of equipoise between the two products due. Therefore in order to determine the potential benefit of one product vs another a clinical trial is required. In this case I believe that a new product is likely to provide equal if not better outcomes therefore it is likely to be beneficial for me to participate within this trial. In addition, any participation in a trial is likely to result in closer scrutiny of my overall health and care which regardless of any possible influence of the trial product is likely to result in a better outcome for myself.

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

Delayed consent is a completely appropriate alternative to immediate consent. There are clearly situations in which research is required to be conducted, such as in an acute emergency, where at the time of administration of the research intervention a patient may unconscious or may not be competent to consent. An intervention may also be time critical so a patient or patient's family may not, at the time of the required intervention, be able to take time to reflect, understand or weigh up the risks/benefits of the proposed research prior to administration of the research intervention. At the time of the required intervention it may not be appropriate to approach the family or patient regarding a clinical trial due to the emergency or acute nature of the event at which the clinical trial is taking place. Without delayed consent this would greatly limit the ability to conduct any research in an acute emergency situation so it is vitally important that this remains a method of being able to recruit patients into a 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.

Patients with impaired capacity should not be denied the opportunity to have evidence based improvements made to their 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.

Although adrenaline has been shown to improve survival to hospital it has not been shown to improve neurologically intact survival to hospital discharge. I and others like me may benefit directly from this research.

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

The opt out process is a poor idea, it may involve a very costly public awareness campaign which is unlikely to have sufficient ability to reach all consumers who may wish to opt-out. Also, such a campaign is totally irrelevant to most people who will never suffer a cardiac arrest. Moreover, a public campaign risks biasing public opinion against medical research

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 -
There are clearly situations in which research is required to be conducted, such as in an acute emergency, where at the time of administration of the research intervention a patient may unconscious or may not be competent to consent. An intervention may also be time critical so a patient or patient's family may not, at the time of the required intervention, be able to take time to reflect, understand or weigh up the risks/benefits of the proposed research prior to administration of the research intervention. At the time of the required intervention it may not be appropriate to approach the family or patient regarding a clinical trial due to the emergency or acute nature of the event at which the clinical trial is taking place. Removing the ability to conduct research on patients who are unable to consent would greatly limit the ability to conduct any research in an acute emergency situation so it is vitally important that this remains a method of being able to recruit patients into a trial.

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 benefits and risks / appropriateness of the research should be evaluated, as it currently is, by a human ethics committee. The ethics committee should work with the researchers to develop appropriate conditions for individual research studies to occur.

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 is a completely appropriate alternative to immediate consent. There are clearly situations in which research is required to be conducted, such as in an acute emergency, where at the time of administration of the research intervention a patient may unconscious or may not be competent to consent. An intervention may also be time critical so a patient or patient's family may not, at the time of the required intervention, be able to take time to reflect, understand or weigh up the risks/benefits of the proposed research prior to administration of the research intervention. At the time of the required intervention it may not be appropriate to approach the family or patient regarding a clinical trial due to the emergency or acute nature of the event at which the clinical trial is taking place. Without delayed consent this would greatly limit the ability to conduct any research in an acute emergency situation so it is vitally important that this remains a method of being able to recruit patients into a trial.

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.

Most patients who are undergoing resuscitation are likely to die. Therefore, research conducted on this group of patients is unlikely to benefit them as current patients. However, if we are not able to conduct research to determine what the best and safest treatments are on these patients then improvements in care for future patients would not be able to occur.

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 people being studied s
2	The research should be for
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 committees are vital to the protection of the potentially vulnerable people that the research is being conducted on. The importance of ethics committees was and is fully demonstrated by the 1987 Cartwright Inquiry.

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.)

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Decision-makers.

Additional comment.

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

- ☐ Consulted by decision-maker
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- ☐ 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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Thank you for your contribution to this consultation.

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Started on 30 April 2017 at 7:50pm | Completed on 30 April 2017 at 10:42pm

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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.

It would contribute to the body of knowledge and hopefully improve treatment for people in the future. It would not be overly invasive for me (no added discomfort) and will not impact on my recovery outcome.

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 having the surgery anyway, and it would be beneficial to others in the future as to which product was more effective in which situations.

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

I don't think that would be appropriate as it may cause unnecessary confusion/distress. I would want to be informed though that I was part of the study (and maybe the outcomes).

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 I was receiving the interactive interventions I would like to think I might get some benefit, if I wasn't it would still be good to have the outcomes measured - for the benefit of others in the future. However I would want the proviso built in that if the

interactive intervention was causing me distress that the researchers would interpret that as non-consent and withdraw me from the project.

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.

For the benefit of future patients

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

I think the opt-out process would be unreliable

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 a level of risk, and people need to be able to fully understand possible benefits/risks and weigh them up for themselves.

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 members reasons for wanting their person to be enrolled might be for different reasons than what the disabled person might have.

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 inform further development of medical treatment. I think there are many people who would want to participate in studies even if they are unable to give consent in a particular moment in time.

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

When the intervention is not presenting possible risk, is not overly intrusive/invasive, when they were going to receive treatment anyway. There needs to be requirements that the researchers have contact with family/significant person to the potential participant (there may be belief factors they know of that could preclude involvement) - if not possible the person should not be included in the project.

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

Behaviour is communication, regardless of whether the person can communicate reasons for 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.

People are more likely to feel they have to consent because a particular intervention has already occurred

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.

Absolutely, the automatic position is that people should be able to give consent - only in extenuating circumstances should participants who can't consent be included

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.

Many people would want this even if they are unable to give consent at a moment in time

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 reasons for including people who can't consent need to be rigorously tested - and the research externally monitored as it progresses. Such projects need to be seen as the exceptions.

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?

Possibility that involvement could result in improved quality of life

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
- [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?

☐ 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 Family/whanau
2 Significant friend
3 EPOA
4
5

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

They need to be people who have a close relationship with the person, preferably with a history and know the person's beliefs/values/what's important to them.

Final comments

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

Please state your name

Organisation (if applicable)

I 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 29 March 2017 at 2:45pm | Completed on 1 May 2017 at 11:03pm

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.

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), and it does seek to address a really important clinical question which promotes the health of the group represented by the potential participant. The procedures described in the case study which are additional to usual care i.e. the extra blood and urine tests do not present more than minimal risk or burden to the potential study participant who is already likely to be catheterised and to have tubes in for the collection of blood for routine clinical monitoring purposes.

Provided that there are safeguards in place such as ethics committee and scientific peer review of proposed observational research in the ICU setting, observational studies such as this which address important clinical questions and place minimal risk or burden on participants it should be able to proceed because it is unethical not to be able to undertake research which provides the evidence for better understanding of disease and the best treatment of patients.

There are a very wide the wide range of conditions in which patients may not be able to consent (emergency medicine, intensive care medicine, paediatrics, dementia), and these are all areas where there may be a paucity of effective treatment options or a lack of evidence for current treatment methods. If scientifically warranted and ethically appropriate observational research is not allowed to proceed in these groups it will 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 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.

The research scenario described compares interventions which are in current usage and for which the comparative efficacy/risk profile has not been established. Given that as a patient I may have been equally likely to receive either of these treatments and provided that there had been a rigorous ethical and scientific assessment of the underlying rationale and design of the study to ensure that the clinical question being addressed by the study was a) worthy of asking and b) going to be adequately addressed by the study design and c) that the study did not present any significant additional risk to me as a participant (i.e. the surgical product I was randomly allocated to would be utilised in accordance with best practice and manufacturers guidelines and I wouldn't be subject to more intrusive or risky procedures that would be normal for a person undergoing this type of surgery, I would be willing to participate.
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 instances where prospective consent is impossible (such as in the emergency or intensive care settings or in the case of some of the participants in this study) but participants may regain the capacity to consent post-treatment, it is respectful of the participants to give them the opportunity to consent. Although they cannot consent to the initial involvement in the research it still gives them some opportunity for autonomy - i.e. delayed consent is a means by which patients can "opt-out" of the study and ask for their withdrawal from on-going research involvement and also potentially for withdrawal of their data from the dataset. It also provides the framework for the participants to be fully informed about what has happened in terms of the research during the time when they were not competent to consent and to ask questions about this.

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

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 an area where there is a paucity of successful treatment options; it is a devastating problem for the patient with it and for their family and loved ones and with an aging population it will become an increasing issue for the health system and society to manage unless treatment improves. So I would be very comfortable to participate in this research as I consider there is a real need for it, the intervention being trialled is not a medication with unknown side-effects and is very unlikely to be "risky" to my physical health. Provided the study was reviewed ethically and scientifically to assess that all interventions were reasonable and justifiable and not unduly "risky" and the protocol allowed for and captured as a finding the withdrawal of participants who were experiencing significant distress in response related to the protocol mandated intervention assessments, with an appropriate threshold for stopping the study should there be evidence that the intervention was doing more harm than good. In addition to the safeguards outlined above 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.
If it was not possible to undertake research in people 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.

As a potential "patient" I would hope that if I ever found myself in this situation (i.e. having a cardiac arrest), or that if my "loved ones" did, that I (or they) would be treated according to methods that were proven to save lives and to ensure a good recovery outcome with minimal on-going "damage" as a consequence of my cardiac arrest. But I am also very aware that at

present we do not have all the answers, and that there are many treatment interventions commonly utilised in emergency medicine that do not have an evidence base for their use other than "historical" tradition and which therefore may actually be harmful. As a member of society I would therefore be willing to participate in such as study provided it had been ethically and scientifically reviewed and approved to ensure that the study was well-founded, designed and not exploitative of my "altruistic impulses".

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

Although an "OPT-IN" bracelet process with some sort of registry or system similar to the recording of willing organ donor's on drivers licences may be "fairer" in terms of ascertaining patients' wishes in this situation it may not be feasible. If it was not feasible, then I think that the proposed "OPT-OUT" bracelet process is a reasonable compromise as an ethical approach to ascertaining the wishes of potential participants provided that there is a very thorough public awareness campaign including on social media and mainstream media and that it is possible for members of the public to obtain the bracelet (for free) both prior to and during the study from a number of public places (e.g. medical centres, hospitals, local council offices, libraries, work and income branches etc etc) in addition to having to specifically requesting 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.

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. However, I have answered this question "No" because there are a number of aspects of the particular research scenario described which concern me. It appears that the drug may present significant safety risks (increased incidence of contemplating suicide), and there is a lack of evidence of benefit that would outweigh this significant risk. I would require further clarifications of the research proposal detail, scientific assessment and rationale for the study design and proposed assessments as the regular 6-hour assessment visits sound like they could be very burdensome and potentially distressing to or exploitative of the participants (particularly in the case of those whose cognitive function was impaired to an extent that meant they could not consent). I would also want to see significant revisions to the outlined process for consultation with family/caregivers. Family/caregivers should have the opportunity to provide consent, and the participant to provide assent if possible. An "Opt out" process is not at all appropriate in this setting of non-acute research into a chronic disability with participants who cannot consent and in any such research in this patient group there should be the safeguard that the next-of-kin or primary family/whanau/caregiver gives informed consent along with assent if possible by the person with Down's 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.

No I do not think that this proposed consultation (which mirrors an opt out process) is appropriate. The proposed process appears exploitative of a very vulnerable participant group and of the caregivers of the potential participants who are in themselves potentially very vulnerable. 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. In order to have this capacity they need time to think about the study, the opportunity to consult with the wider whanau if appropriate and they should probably undergo counselling and assessment of some kind to support them in their understanding of the study, to address their potential feelings should they enrol their child in the study and their child experience a regression at the end of the study after showing improvement on the study drug, and to assess that they are not so desperately impacted by their child's disability that they would sign-up for anything.
Enrolment into this study is taking place in the context of a permanent disability and a vulnerable patient group – there is no justification for using an "opt out" style process for enrolment. Only those potential participants whose primary caregivers are willing after full consideration of the study 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 must be allowed to proceed with adult participants who are unable to provide informed consent. There are many clinical situations in which patients are unable to provide informed consent, due to the nature of their condition, and in which there is a real need for new or improved treatments. In some cases there are no treatments available for some of these conditions. This means that patients are not treated or 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.

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

Any such research should have gone through rigorous ethical and scientific assessment and approval processes to ensure that it is valid in terms of methodology and design, clinical need and not unduly burdensome to or risky for participants given the possibilities of benefit (if any). It should also be carefully scrutinised as to whether the research needs to be conducted in such a vulnerable patient population, and it should be possible to determine that there are no inappropriate financial or professional incentives that are significant motivators for the research. Additionally any institutions participating in such research should be able to demonstrate that they are properly resourced to conduct the research successfully and that they have appropriate procedures in place to safeguard the well-being of participants and to minimise risk of adverse outcomes and participant exploitation.

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.

All potential participants in research should be offered the same level of safeguard and protection that is appropriate to the risk level of the research irrespective of the organisation the research comes from. The best interests of the participants should prevail.

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 do think that as a general principle there should be respect shown for means of communication by those who may not be able to fluently verbally communicate due to their health condition or situation but I have said unsure because I am uncertain as to how the law could be worded in an appropriate way to address the wide range of health conditions and clinical situations which would apply so that it would not be either overly prescriptive and effectively stymie research in patients who are not competent to consent. For instance many patients in the emergency or ICU settings if conscious will be in extreme pain and express distress due to their illness or injuries, they may be experiencing delirium; in these circumstances the attending clinicians have the responsibility in relatively pressured situations for making a decision around whether the patient's behaviour represents "an expression of their thoughts and a refusal" of a procedure or is just representative of the patient's situation e.g. they are delirious or it is an expression of distress coincidental to the research. It is hard to see how the a law could be adequately worded to address the potential complexities of such situations by adequately and appropriately detailing and discriminating between behaviours to define those that indicate that the patient is refusing participation.
Conversely in an example such as a research project in a non-acute and chronic setting such as research in patients with Dementia or people with Downs Syndrome, it is important that there is some recognition by the researchers that the participants should be able to communicate their wishes through non-verbal e.g. behavioural means of communication and that those people who know the patient (e.g. family/caregivers etc) may have an understanding of the messages that the patient wishes to communicate through their behaviour. Someone in this situation may not have the understanding of the situation and the language skills to be able to say "don't take my blood I don't want to be in the research" but they can clearly indicate that they do not wish the blood sample to be taken by physically resisting or showing signs of fear (screaming etc when they see the needle and syringe) and this expression of their wishes should be respected.
Rather than amending the law, it is probably more appropriate for this issue to be addressed by the ethics review process. A careful ethics review of research applications of such proposed studies including an evaluation of the researchers' cognisance and ownership of responsibility to respect participants' wishes as demonstrated by their grasp of the different scenarios which may occur and their documented proposed enrolment procedures to address such scenarios should be undertaken.

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 gives the participant the opportunity to formally express their wishes in terms of matters such as requesting that their data be withdrawn from analysis and is a practical was to address some of the issues raised by conducting research in participants in the emergency or intensive care unit settings.

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.

Any research involving incompetent persons should be carefully assessed for scientific validity and ethical reasonableness. In most circumstances it would be ethically reasonable to require the researcher to demonstrate this. This approach is reflective of the Declaration of Helsinki. There may be some occasions when public health needs such as a pandemic situation may over-ride this requirement, and there should be allowance in the law to take account of this but under usual circumstances this requirement should prevail.

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 adequate safeguards are in place to ensure that the incompetent person is not being placed at undue risk or exploited, that any known wishes of theirs are respected, and that that they are given the opportunity to withdraw their consent or to provide deferred consent should they regain compentence. The observational scenario of patients with sepsis in ICU (case study A) is an example of such research that should be permitted.

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 review and approval process provides a degree of protection to vulnerable patients.

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 have said unsure because there is such a wide range of possible research that may be conducted that to my mind it is not possible to answer yes or no to question 7.1 as it stands i.e. in research such as observational research it is usually impossible to demonstrate that the participant will be better off than if they did not participate so the key is really to ascertain if they will be worse off (i.e. put at more risk or exploited in some way) whereas with a clinical trial testing a new treatment against the gold standard of care then it is far more appropriate to ask the question of whether it is better for a participant to be in the study and potentially receive an experimental treatment rather than to not be in the study and just receive the gold standard therapy.

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.

Once again the type of research, particularly the patient group under research, is an important factor here. Hence my choice of "unsure". In terms of the acute emergency/intensive care settings it is somewhat impossible to make a judgement that will satisfy "society" about the reasonableness or ethical validity of allowing proxy consent by another e.g. for family members to give consent on behalf of their "normally competent" relative as different individuals and different cultures place different weight and significance on family ties. However, in the future it should be possible utilising the technology that is available and the unique NHI number assigned to health care consumers to ascertain, document and make available to health care providers and researchers, the wishes of each individual with regards to such issues. This would to some extent be analagous to the current system of identifying people who are willing to be organ donors by their driver licensing system.
Conversely, in the case of intellectual disabilities/degenerative neurological illness such as dementia and potentially in significant psychiatric illness; our society frequently places a significant on burden on family/whanau as being the primary caregivers and advocates for these people, particularly in the case of family/whanau who live with the potential research participant. We as a society are "trusting" these people all the time to "do the right thing" by the person they care for e.g. not to leave them in unsafe situations, to feed them, tend to their personal needs etc Unless there is some sort of evidence that the wishes of the patient would have been otherwise, then in return for placing this not inconsiderable responsibility on family/whanau, we should have a framework in the law which recognises and awards some authority to the primary caregiver from the family/whanau to make decisions that they consider to be in the best interests of the patient and consistent with their wishes.

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 a person has taken the step of arranging an EPOA or welfare guardian for themselves then that person (the EPOA or welfare guardian) should be consulted if they are present or contactable at the time the decision needs to be made.

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.

There needs to be a distinction drawn between types of research in terms of the differing complexity and burden of responsibility for giving consent on behalf of an incompetent participant. I.e. allowing a few extra blood samples to be drawn from the participant is significantly less weighty than agreeing to the trialling of a highly experimental procedure or drug. There also needs to be a distinction drawn between asking someone to consent on behalf of another in an acute vs chronic situation (such as long-term disability or mental impairment). In lower risk situations and in chronic situations provided it can be clearly demonstrated that there is no financial incentive for giving consent on another's behalf then in addition to being consulted and having the power to veto participation in the research they should have the ability to provide (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.

Additional comment.

See previous comments concerning EPOA and welfare guardians. The participant's EPOA may often be a family member e.g. their spouse or adult child.

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.

See previous comments concerning EPOA and welfare guardians. The participant's EPOA may often be a family member e.g. their spouse or adult child.

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.

This is a very complicated question as the possible circumstances are so broad - this is the type of question that needs to be answered on a study by study basis and in the context of a mandatory ethics review.
I have chosen "unsure" because the breadth of possible research types and participant settings makes it very difficult to answer this question.
For example in a study in an acute emergency setting, it would seem likely to be inappropriate for the patient's GP to be involved in the decision-making; however, in a study involving chronic intellectual disability or dementia it may be quite appropriate to involve to some extent someone such as the patient's GP or an allied health professional who is involved with the patient in the decision-making.

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.

see above 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 have chosen "unsure" because the breadth of possible research types and participant settings makes it very difficult to answer this question.
For example in a study in an acute emergency setting, it would seem likely to be inappropriate for some "other person" other than family, the primary clinician and the researchers, to be involved in the decision-making; however, in a study involving chronic intellectual disability or dementia etc it may be quite appropriate to involve in the decision-making (on a consultative

basis) someone such as a non-family carer who is involved with the patient to a significant extent. An example of such a study where this could be appropriate would be case study C, which involves trialling "interactive care" in rest-home residents with dementia. A carer familiar with a particular resident of the rest-home may know whether this particular person would be at significant risk of finding the intervention distressing and therefore detrimental to their well-being. As it would be difficult to construct legislation that would allow for such flexibility in deciding who can be involved in this process, then presumably the aim of any amendment to the legislation should be to allow for the Ethics Committee to decide who should be involved given the particular set of specifics of each research project.

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.

Because of the breadth of research covered by this consultation document I am not comfortable to rank decision-makers as I think for different types of research the rankings should be different.
For example in the context of an emergency or ICU type of research project then the responsible clinician should have the final decision (after consulting other decision-makers) whereas in other settings for example the scenario described in case study C it is more appropriate for the EPOA (if there is one) and family/whanau to be making the decision.

Final comments

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

My perception is that the current legal situation in NZ does not necessarily best serve New Zealanders and that there are amendments that are needed to the legislation.
- all research in participants who are unable to consent should require ethical approval from an HDEC
- there is should be legal allowance for delayed consent and proxy consent in those circumstances which warrant it
- UK and Australian law should be examined as they appear to offer some improvements over current NZ legislation
- the current legal position regarding observational research in participants who cannot consent is unethical as observational research is an essential prerequisite for the design of interventional clinical research that can lead to improvements in care and treatment of life-threatening, hard to treat and poorly understood health conditions

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 May 2017 at 10:50pm | Completed on 1 May 2017 at 11:14pm

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

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. Depending on the research, there may be 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.

Key caregiver with welfare guardianship/Epa and an independent advisor should both agree to decline/proceed, based on criteria that guides such decisions.

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.

Much research falls outside of life/death matters and informs service development and treatment, also stops or prevents poorly researched treatments from being used, with funding implications.

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

Sometimes interpreting a loved ones expressions can be pure guess work, however non verbal expressions can also be accurately interpreted. So, it depends on the research and taking a do no harm approach.

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'd not consider consent to be informed, unless the person has written a 'statement of wishes' in regard to participating in research when deemed to be temporarily incompetent.

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.

Surely people deemed incompetent have just as much right to participate and in doing so potentially contribute to improved welfare of all citizens.

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.

All research should require ethics 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?

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.

☑ 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 Epo welfare guardian
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)

Parent

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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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 12:44pm | Completed on 5 May 2017 at 3:54pm

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

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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.

AWHC oppose undertaking medical research on any NZers without their informed consent. That vulnerable groups of consumers can, & are, being exploited for research under the current law goes against the principles of the Nuremberg Code, the founding document that gave rise to modern medical research ethics. It is clear that the law as it stands is sufficiently weak & uncertain as to allow "studies to proceed in relation to participants who are unable to consent if participation in the research is in their "best interests"" where the researcher is able to make the decision as to what constitutes the patients "best interests".
AWHC believes that no incompetent adults should be enrolled in research until there are sufficient protections and safeguards established in law that protect their rights & interests, health & well-being.
The Nuremberg Code was followed by the WMA's Declaration of Helsinki which clearly states that:
- "while the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects";
- "some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm... All vulnerable groups and individuals should receive specifically considered protection."
- "participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees."

Yet despite these existing protections, which NZ's Medical Association ratified, medical experimentation on competent women at National Women's occurred without their knowledge or consent in the 1960s & 70s.
Our Code of Health & Disability Services Consumers' Rights still allows research on incompetent adults on the basis that the

researcher decides it is in the patient's best interests. AWHC doesn't believe that researchers are capable of making an unbiased decision that is truly in the best interests of the patient. In addition, it is AWHC's view that the current HDECs do not prioritise the protection of research subjects.
Once an adequate ethical & legal framework is in place (including definitions of terms like "minimal risk/burden", "benefits", "best interests", & who constitutes an authorised legal representative) further nationwide discussion, including patient & consumer advocates, should revisit the circumstances, if any, in which research involving incompetent adults might be permitted.
If an adequate ethical and legal framework was established that provided sufficient protections for incompetent research subjects, including a Special Ethics Committee to oversee approval to such research proposals (see Q 9), AWHC might take the following view on research such as described in Case Study A:
The research is relatively non-invasive in that it does not involve varying the treatment protocol, & there is very low level of risk involved. It involves the collection of data from urine obtained through dialysis that is already occurring. However, the case study text infers that further blood tests would be taken to provide data on antibiotic concentrations in the blood; blood tests that would otherwise not be performed. The knowledge gained could improve treatment for future patients, & it seems that significant benefit to future patients may result. Informed consent must be obtained from next of kin or anyone holding EPOA and the patient's informed consent when competence is regained. However, if the patient, upon reaching competence, withholds consent, data collected from that patient must be withdrawn from the study and destroyed.

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 insufficient information provided in this case study; however, it appears that the same information could be obtained through enrolling competent consenting patients undergoing elective surgery (refer to Schiariti A.; Surg Neurol Int. 2014; 5: 171.), in which case clinical trials on incapacitated/incompetent patients should not be considered.
Randomising patients without their consent is unethical because, in many patients, there could be a necessary variance from what is best practice care for the surgeon involved. It is unclear from the information provided if the researcher, Dr B, is the surgeon who will perform the surgeries involved in the study. There are several reasons why any given surgeon chooses to use particular products and those reasons may impact upon outcomes in different patients operated on by different surgeons. If patients are to be randomised a surgeon may end up using a product s/he was less familiar with or had less confidence in and this could introduce an outcome bias.
It is clear from other similar research that this research could be undertaken in patients who are competent before surgery and as a starting point Dr B should undertake fully consented research on competent patients.
There are insufficient clear benefits to incapacitated/incompetent patients that outweigh their right to provide informed consent.

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

There can be no such thing as "delayed consent"; it is effectively an oxymoron. Asking for consent after the fact is like a child asking a parent for a biscuit after having eaten one; if the answer is no what happens? You can't change what has already occurred.
In observational studies it is possible to remove a subject's data from the results of the study, but in interventional research the outcomes of treatment will be the same. Where treatment or procedures in a study (particularly a randomised study)

might vary from what would have happened in a non-study situation, once it has happened it can't be reversed. There may well be compelling reasons why a person would not have consented; they opposed randomisation or had a personal preference for a specific procedure or product to be used; there were ethical issues that concerned them about the manufacturer/suppler or manufacturing process or materials used… or simply did not want to take part in research for personal or cultural reasons. It goes without saying that if "delayed consent" is sought, then a subject's information and any data obtained must be removed, and if the follow-up is long term (beyond the regaining of competence) the subject should be withdrawn. The inclusion of people not competent to consent prior to the research should never be justified on the basis that "retrospective consent" can be sought.
In reality, the only consent that can be obtained in retrospect from a previously incapacitated or incompetent research subject is consent to remain in the research. It is simply disingenuous semantics to suggest that patients could provide delayed or retrospective consent.

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

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 should start with a pilot study among those patients capable of providing consent. Dr C is clear that "there is very little evidence about the benefits or risks associated with 'interactive care' " and dementia patients are a very vulnerable group. A pilot study among consenting patients would give Dr C sufficient information to assess levels of distress among participants in the "interactive care" group as well as any benefits that such care might ultimately afford the patients.

A well designed study undertaken with sufficient advance notice should be able to provide enough information to answer the question as to the benefits and risks of the intervention without including patients unable to provide informed consent.

In a situation in which there is a strong legal and ethical legislative framework that offers sufficient protections and safeguards for vulnerable groups, results from a cohort of participants able to provide consent might then form the basis for further research in which informed consent from next of kin or those with EPOA might be a valid approach to understanding the benefits and risks of intervention for those unable to consent. However, the results of a pilot study might deliver data that rules out intervention on the basis of risk versus benefit, in which case a highly vulnerable incapacitated/incompetent cohort would never need to be subjected to research of little or no benefit to them.

A further consideration is that frequent assessments in themselves might raise levels of frustration, anxiety or emotional distress in this highly vulnerable group of patients and it's clear that the researchers can't say that the research is in any way in the "best interests" of the patients.

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 is totally unethical to withhold a standard or best practice treatment from patients without their consent and, in particular, in a life or death situation, such as when a patient's heart has stopped beating. While the issue of whether or not the use of adrenaline leads to overall lower survival rates and increase in brain damage is an important one to research, there is insufficient information provided on the effects of not using adrenaline and using a placebo (which by definition is a non-therapeutic substance or treatment) instead. This research has absolutely no benefit for the subjects involved in the research and can only possibly benefit future patients. The threshold for benefit versus risk, in the case where consent cannot be obtained, must necessarily differ if those provided a treatment cannot weigh up the pros and cons and make an informed decision. In this case the benefits for the subjects are too low and the risks potentially too high.

AWHC objects in the strongest possible terms to this type of research in which subjects unable to consent may be randomised to not receive best practice care in a life threatening situation. It is hard to imagine any scenario in which such research could be considered ethical. In addition, as a double blind trial, the attending physicians would not know whether adrenaline or placebo had been given and will therefore have no idea the exact cause if the patient fails to respond to the treatment.

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

An "opt out" process, in virtually any medical scenario, is highly problematic and is in no way a valid or ethical alternative to the provision of fully informed consent. It is predicated on the idea that 100% of the population that may be at risk of sudden cardiac arrest will be made sufficiently aware of their choices that they will be able to, and motivated to, make an informed decision to "opt out" or, by definition, choose to actively "opt in" by doing nothing. Given the known apathy of populations to exercise their mandated right to do such things as vote (a far less personally risky action than to choose to participate in research in a life-or-death situation), it is extremely unlikely that anything close to 100% of the "at risk" population would be reached in a public information campaign. Therefore, the probable low level of active decisions to "opt out" cannot be taken as tacit consent to participation in a medical experiment by the remaining (quite likely majority) of the "at risk" population.

Additionally, many of the at risk population simply do not know that they are at risk until they have such a medical event. People ignorant of their risk status would not be easily communicated with via a public campaign.

A further stumbling block to this proposal is that it would seem likely that few people would want or would be bothered to consistently wear an "opt out" bracelet.

The "opt out" idea is a highly disingenuous way of abrogating responsibility for the need to obtain informed consent from patients involved in potentially risky medical research. It has been acknowledged that it would be difficult if not completely impossible to obtain informed consent in the described scenario and the "opt out" solution is an unethical attempt to get around deservedly stringent regulations regarding the participation of human subjects in medical experiments.

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 are significant in a group of already highly vulnerable people, with limited or no benefit. It is clear that the benefits are not well understood and that if there were any, they would likely be short lived – what would be the effects on the adults with Down syndrome if they enjoyed improvements in cognition and learning ability only for those effects to dissipate once the drug was no longer administered? This surely amounts to a cruel punishment, and if the subjects are not competent enough to provide informed consent, how will they cope with an improvement and followed by a decline in their abilities? Given that clearly little is known about the adverse effects of the drug, and that many Down syndrome people have other physical health problems, such as poor immune function, congenital heart defect and epilepsy, it would be unethical to risk side-effects that would further compromise their quality of life without their informed consent.

It is entirely unethical to involve anyone without their fully informed consent, and a full and conscious knowledge of the risks and benefits, in research that may raise their risk of contemplating suicide. It is hard to imagine that any transient and short-lived cognitive benefit to Down syndrome adults could be perceived as balancing the risk of self-harm or even thoughts of self-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.

Some of the issues that are raised in E2 above apply here: if the subjects are not competent enough to provide informed consent, how will they cope psychologically with the impacts of the research and administration then withdrawal of the drug (e.g. an improvement and followed by a decline in their abilities; or significant risks to their health and quality of life, such as increased thoughts of suicide) if another person sees fit to consent on their behalf?

The family/whānau of vulnerable patients/consumers are subject to potential coercion and duress. Most want what is best for their loved ones, but may not be best placed to make important decisions regarding research of which they may have little understanding, in particular when they harbour hope that improvement is possible when the prognosis is poor.

In this case study, while family/whānau may be swayed by thoughts of possible improvements to cognitive and learning abilities, the risks are still significant and the benefits insubstantial and ephemeral. While people with Down syndrome have a reduced mental capacity, many lead happy, productive, quality lives and this vulnerable group should not be viewed as experimental subjects by anyone and only they should have the right to provide informed consent for medical 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.

As stated at the outset of this submission, the AWHC holds a philosophical opposition to conducting medical experiments, including within the auspices of clinical trials, on any New Zealanders without their fully informed consent. That vulnerable groups of consumers can, and are, being exploited for research gain under the current law* goes against the principles of the Nuremberg Code (1947), the founding document that gave rise to modern medical research ethics. It is clear that the law as it stands is sufficiently weak and uncertain as to allow "studies to proceed in relation to participants who are unable to consent if participation in the research is in their "best interests"" where the researcher is able to make the decision as to what constitutes 'in the patients best interests'.
The AWHC believes that absolutely no incapacitated/incompetent adults should be enrolled for medical experiments/clinical trials/research until there are sufficient protections and safeguards established in law that first and foremost protect their rights and interests, health and well-being.

* Johnston, M.: Consent for drug trials on coma patients to be reviewed, New Zealand Herald, 15 December 2014.

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 sufficient protections & safeguards are established in law research involving incompetent adults might be permitted to proceed: e.g. there is a direct benefit to the incompetent adult, & without research there would be no other opportunity for the incompetent adult to benefit, & if the risks are significantly outweighed by the benefits. However the most stringent safeguards must be applied & each case should be assessed on an individual basis. Observational studies are of lesser concern as such studies do not require any variation on best practice treatment of the research subjects.
However, even observational studies raise issues of consent & whether or not it is culturally appropriate & sensitive for some patients to be included without their consent when they might hold different values & views around the collection, storage & use of personal data & human material such as blood, urine & tissue.
Where there is no direct benefit to the incompetent adult but to future patients in the same or similar situation, research might be allowed to proceed under strict ethical control (see Q 6.2) where there is also very limited or no risk involved, such as in the case of observational studies, & where sufficient other safeguards (e.g. next of kin/EPOA consent) are in force.
However, as discussed in Q A2, it is critical that clear definitions of terms such as "minimal risk", "burden", benefit" & "best interests" should be set out. Additionally, the person able to make an "in the patient's best interests" decision must be clearly defined, including that that person cannot be associated with the research, and should have knowledge of the patient, & their condition.
Specifically, research should only involve incompetent adults if:
1. the research is observational & does not involve invasive procedures and does not involve any deviation from best practice care of the patients; that data will be collected in the course of the normal best practise care provided.
2. the same research cannot be undertaken with adults capable of providing informed consent;
And/or
Research has already been undertaken in competent, consenting adults, & further research involving incompetent adults would significantly add to the body of knowledge & benefit those patients or future patients with the same condition (subject to 3 below).
3. the research is directly related to the condition/s that the incompetent adults have, &/or directly relates to the reasons they are incapable of providing informed consent.
4. there is direct benefit for the research subjects & negligible risk, or that the benefit to the research subjects is significantly outweighed by the risks; that a research subject will benefit as much from being included in the research as not being included;
Or
There is no expected benefit for the research subjects but that there will be a significant benefit for future patients with the same condition, & the risk to the research subjects is negligible.
5. the research does not involve "non-inferiority" research, & that benefits to the subjects are more than inclusion benefits.
6. all proposed research is subject to approval by a "special ethics committee" – see response to Q 6.2.
7. notwithstanding the submission made in Q 3.1, in all cases where "retrospective" or "delayed" consent from the incapacitated/incompetent adult is obtainable upon regaining competence, that consent is sought without coercion, duress, discrimination, harassment, or exploitation.
8. all efforts are made to ascertain the incompetent adult's attitude to participation in research or clinical trials, such that it may have been discussed explicitly or otherwise at a time when the subject was competent.
9. any indication that the research subject does not consent, appears to object, shows signs of resistance before, during or after the research, they must immediately be withdrawn.

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 circumstances, role, employer or title of the person or group undertaking the research do not in any way at all alter the vulnerability of adults who are unable to provide fully informed consent to participate in experimental research. There should no difference in the application of any code of rights, legislation or safeguards regarding the recruiting and involvement of incapacitated/incompetent adults in any and all research and the foremost consideration should be the safety and well-being of the subjects/proposed subjects of the research. The same laws should apply to all research involving adults unable to provide informed 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

If there is any doubt whatsoever about the willingness of any research subject to participate or continue participating, the decision must err on the side of caution and the subject must never be enrolled in or must be withdrawn from the research.

When considering such vulnerable groups of adults, the threshold for participation must be especially high in order to ensure all such adults are protected to the fullest extent possible. In order to protect all potential research subjects, it may be that some who may have consented had they had the competence to do so are ruled out, but this is necessary to ensure that no person is included in research that would not have consented had they been competent to do so.

It is widely reported by health professionals working in the field, that unconscious patients can still have some awareness of what goes on around them, in particular through the sense of hearing. Likewise, conscious but impaired people, such as dementia patients or intellectually disabled people have many ways of expressing their dissent even if they are unable to verbalise it with the same degree of articulateness that a fully competent adult might. It cannot be assumed that a patient who cannot provide clear, audible or visible responses in the way that fully competent patients can, cannot express themselves in any manner at all or that they are entirely unaware of what is happening. To ignore subtle signs of distress or resistance risks refusing the patient the opportunity to express their lack of consent in the only way that is possible.

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.

Although in earlier questions in this submission the AWHC has indicated that this should be sought and the decision respected and abided by, in general we have a philosophical objection to the concept of "delayed" or "retrospective" consent.

It is simply not possible to provide informed consent after the fact.

As stated in Question B3, there can be no such thing as "delayed consent" or "retrospective consent"; it is effectively an oxymoron. The consultation document states that "In New Zealand, delayed consent is not a legally valid form of informed consent. It is not possible to provide informed consent retrospectively, because the events have already taken place, even if the consumer, upon regaining capacity, does not have an objection to having been included in the research."

There needs to be an alternative term that more accurately describes the situation where patients, on regaining competence, are informed that they have been participating in research without their consent and that they can withdraw and have their data withdrawn from the study.

In a few very limited cases the obtaining of this type of "retrospective" consent may be sufficient to right an incorrect assumption that the subject would have given consent had they been able to prior to the commencement of research. In a practical sense, if the research is entirely observational and the data can be removed from the study if the adult, once competent, withholds consent, that might seem to remedy the situation entirely. However, in some cultures the collection of data may represent a breach of their beliefs and the removal of data from the study insufficient to remedy the wrong.

The inclusion of people not competent to consent prior to the research should never be justified on the basis that retrospective consent can be sought. Only in life or death situations, where lack of action or treatment would likely lead to the death or serious further disability of a patient, should action be taken prior to obtaining consent, and research in itself is not a life or death situation.

It is also absurd to assume that all patients have some degree of altruism and would happily consent on the basis of contributing to the "the greater good". There are constant examples of the lack of altruism among many citizens, and those citizens are as likely to find themselves in situations in which they are incapacitated /incompetent as any citizen whose altruism is demonstrated. In addition, one person's altruism may not extend to happily consenting to research that may bring no direct benefit plus known or unknown risks, and unless consent is acquired while they are competent it is all but impossible for anyone else to know if that person would consent on the basis of "the greater good".

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 is imperative that if research involving incapacitated/incompetent adults is proposed, and considered, that absolute proof be provided by the applicant that:

- they have exhausted all possible means of obtaining the required data from enrolling competent participants;
- it is critical to undertake research in a specified group of incapacitated/incompetent adults in order to benefit the specific cohort of incompetent adults with the particular conditions associated with their inability to provide informed consent; and
- adequate preliminary studies have been undertaken in competent and consenting adults in order to establish the probable risks and benefits prior to any research involving incapacitated/incompetent adults being proposed.

The AWHC also believe that such an ethical standard be made a legal requirement. There seems little point in having ethical standards that have no legal support, cannot be enforced and rely entirely on researcher compliance.

It may be that, in some cases, obtaining informed consent from competent patients prior to the situation in which their condition or impairment renders them incapacitated/incompetent slows down the progress of the research. In this case research must be delayed in order to amass sufficient consenting subjects to undertake the research rather than rely on incapacitated/incompetent subjects. The primary concern here is, and must always be, the welfare, health and well-being and rights of the research subjects, not the convenience of the researcher or expediting his or her research.

Changes to the Standard Operating Procedures of the HDECs in 2012 has resulted in a shift away from protection of consumers and proposed research subjects towards expediting research. Issues of concern were raised in an open letter to then Minister of Health, Tony Ryall, by five bioethicists. Their concerns included a reduction in ECs from seven to four, leading to a reduced level of scrutiny of clinical trials, expeditious review by the chair, and some research not being reviewed at all in order to cope with the increased workload. As a result of the changes, research protocols for clinical trials that are categorised as low risk, also receive only expedited review by a committee chair.

There must be a shift back to making the welfare, health and well-being and rights of proposed research subjects the foremost issue for consideration in the HDEC approval process.

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.

As previously stated in this submission, the AWHC believes that absolutely no incapacitated/ incompetent adults should be enrolled for medical experiments/clinical trials/research until there are sufficient protections and safeguards established in law that first and foremost protect their rights and interests, health and well-being.

Even in the event that such legislation is enacted, insufficient information is provided in this document to adequately and definitively answer this question. Whether such research should be permitted would depend entirely on the nature of the research. As AWHC stated in question 1.2 above, the only research that we believe should be permitted in incapacitated/incompetent adults is that of an observational nature, in which there is no deviation from best practice care of the specific cohort of patients. It is accepted that such research is unlikely to benefit the research cohort, but may benefit future adults with the same impairing conditions.

If the requirement that only observational studies are permitted in incapacitated/incompetent adults is met then the answer to Question 5.1 might be yes.

However, if the proposed research goes beyond the observational and involves intervention, variation to best practice treatment, randomised controlled trials, non-inferiority trials, etc. and there is no benefit to the research subjects or the benefit is only an "inclusion" benefit, and inherently, because the research is interventional, some level of risk must be involved, then the answer is a categorical 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	The group that the rese
2	That the research is dir
3	That the results of the r
4	
5	
Any others?	The AWHC holds seriou

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, ethics committee approval must be obtained! It is unconscionable that research involving incapacitated/incompetent adults not be subject to the same rigours of ethical approval to which any other research involving competent consenting adults is subject. While it might currently be possible for medical, health and disability research to go ahead without ethics committee approval because the researcher is not a health and/or disability services provider and is, for example, an academic, it is imperative that ethics committee approval be mandatory no matter the researcher or setting in which the research is to be carried out.

The AWHC believes that the ethical threshold for research involving incapacitated/incompetent adult research subjects must be much higher than that required for competent adults. Such vulnerable sectors of the community must be afforded greater protections than those groups of competent adults who can make decisions for themselves and be their own advocates.

The AWHC believes that the current Code of Rights and HDECs do not provide sufficient protection for vulnerable adults incapable of providing informed consent.

Right 7(4) of the Code explicitly applies to the provision of health and disability services, not research, although right 9 does say that all rights in the code extend to research. However, greater clarity regarding rights of incompetent/incapacitated adults within the code should be addressed irrespective of any other legislative provisions for the protection of incompetent/incapacitated adults.

The AWHC requests that a separate and independent "special ethics committee" (separate and independent from the existing HDECs) be set up solely to consider research in these vulnerable incapacitated/incompetent adult cohorts. This committee would have a core membership, including entirely independent medical ethicists, patient advocates, lay persons and medical/health/disability representatives, and for each individual research proposal would include co-opted members, such as entirely independent lay representatives and patient advocates with a special interest in the vulnerable group to be involved in the research, lay persons or ex-patients of a similar medical demographic to the proposed subjects (where possible), and medical/health practitioners with expertise in the vulnerable group to be involved in the research.

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?

AWHC's view is that only observational, non-interventional research should be permitted in incompetent adults. AWHC opposes the "best interests" test because the term is ill-defined & open to significant variations in interpretation depending upon who is making the decision. In particular, this assessment should never be left to the researcher. AWHC does not believe that researchers are capable of making an unbiased decision that is truly in the best interests of the patient; researchers necessarily have a conflict of interest.
In addition, the concept of "minimal" or "negligible" risk or burden is also ill-defined, & a relative concept that may vary significantly depending on who is making the assessment, & the range of adverse effects or events or the degree of burden that may be suffered. It is entirely possible for unforeseen adverse effects to be suffered by research patients, eg the phase I trials of TGN1412 which "caused a near fatal systemic inflammatory response in all six healthy trial volunteers" (Br J Clin Pharmacol. 2013 Aug). AWHC oppose all 1st in man trials in incompetent adults for this reason (see Q 9). However, even phase II & III trials can be subject to unforeseen, potentially catastrophic adverse events, as evidenced by Case Study E in which there was an increased incidence of suicidal thoughts in previous trials. In another example, in a 1993 phase II clinical trial of Fialuridine, out of 15 patients, 5 died & 2 required liver transplants despite a pilot study of 43 of shorter duration

revealing no serious adverse effects (Drug Saf. 1997 Jul; J Young Pharm. 2010 Jul-Sep).
In the event that sufficient protections & safeguards are provided, & in the circumstances of the limited research AWHC considers might be permitted the decision regarding if participation is in the "best interests" of the subject should be made by an EPOA or authorised representative, & an independent physician who has knowledge of the condition or impairment the subject has. As set out in the Australian guidelines, if consent is provided by an EPOA or authorised representative that consent should be "witnessed by a person who has the capacity to understand the merits, risks and procedures of the research and is independent of the research team, and who knows the person and is familiar with his or her condition."
AWHC is of the view that there are no circumstances in which it is acceptable to impose risk or burden upon a research subject who has no opportunity or ability to weigh up the benefits & risks of their involvement in medical experimentation. Likewise, it is not acceptable to assume that a person is or would be sufficiently altruistically motivated to accept risk & burden of pain, discomfort or adverse effects of research with little or no benefit to themselves, 'for the greater good', unless this view has been explicitly expressed prior to their loss of competence.
However, in the case of observational studies where it is argued that there are no risks or burden, the least that is owed the incompetent adult is that people with sufficient knowledge of the patient & the proposed research including its risk, benefits & likely outcomes make that decision on their behalf.
In summary, the criteria should be that the proposed research causes no disadvantage, discomfit, pain or adverse effect on the research subjects. In effect there should be no disadvantage to the patient notwithstanding the potential for breaching cultural beliefs as commented upon in Q 3.2; this is the only way in which it can be assured that an incompetent adult is not subject to harm that s/he has no ability to consent or object to.
Inclusion benefit – that the research subject will receive better care & monitoring if they take part in the research than if they did not – should never be used in any risk:benefit assessment & never used as any form of justification for inclusion in the research.

7.3 Please state the reasons you formed this view.

Determining whether or not an incompetent/incapacitated patient should participate in research should never come down to a mathematical formula: that if perceived or expected benefit exceeds the expected risk or burden the patient should be included. The value placed on any benefit or degree of harm from burden, or an adverse event or outcome, is a qualitative as well as quantitative assessment that competent adults make when making an informed decision and it varies according to each individual's values, circumstances and beliefs.

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.

Despite what researchers might believe about themselves, all manner of biases are reported in the medical literature and few if any medical researchers could be said to be entirely unbiased. Many biases are sub-conscious and to place the burden of decision making about what is or is not in the best interests of patients in the hands of a single, interested researcher leaves both the researcher and their research subjects open to harm. Dependent on the nature of the proposed research, a range of people, preferably with complete independence from the research and researcher, should be involved in the decision to involve incapacitated/incompetent adults in research.
Similarly, the decision should not be solely made by the family/whānau of the proposed research subject. In some circumstances, the proposal to enrol an incapacitated/incompetent adult in research may be because their condition or impairment is life threatening. In such situations the family/whānau will be under stress and may not be capable of making objective decisions; may not be in a position to ask the questions that the proposed subject might ask were s/he competent. Such stress may constitute being asked to consent under duress, in particular, if the prognosis for their loved one is poor.

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.

AWHC finds the table in Q 8.3 overly prescriptive and does not allow sufficient flexibility for vastly differing circumstances of incompetent individuals that might be considered for inclusion in research. The decision making process should be necessarily more complicated than these questions allow for; decisions for individuals need to be made on a case by case basis rather than according to some algorithm.

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 Independent patient ad
3 Family/whānau
4 Provider not involved in
5 Special ethics committe

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

The decision should be made in consultation with a variety of people; for example, an EPOA night consult with the family/whanau and/or an independent patient advocate, or the patient's GP, or responsible clinician in making the decision. Each patient's circumstances will differ and thus the decision making process and who is consulted will vary on a case by case basis.

The AWHC opposes the veto option for deciding upon whether or not an incapacitated/incompetent adult is enrolled in research. Notwithstanding the AWHC's philosophical opposition to research involving incapacitated/incompetent adults, if there is to be such research there should be a specific responsibility placed on a person or people to provide consent. A veto is akin to an "opt out" option (see Question D3), and the gravity of such a decision to involve an incapacitated/ incompetent adult in research deserves more serious consideration by those involved in the decision making.

Final comments

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

AWHC has specific concerns about the involvement of incompetent adults in research. While we accept the potential benefits of increasing knowledge on the conditions suffered by incompetent adults, the overriding concern must be for the health & welfare of the patient, not the acquisition of knowledge no matter how well intentioned that might be.
While it has reservations about even the least invasive observational research, AWHC categorically rejects permitting the following types of research on incapacitated/incompetent adults:

- 1st in man or phase I clinical trials;
- non-therapeutic trials, eg non-inferiority trials;
- research in which adverse effects could possibly exceed any potential benefit;
- research in which known or expected adverse effects include death, permanent disability or impairment, or worsening of the existing condition;
- research where the only or most likely benefit to the incompetent adult is an "inclusion benefit".

It is the AWHC's view that HDEC approval is insufficient protection for incompetent adults, & that a Special Ethics Committee (see Q 6.2) must be set up to specifically consider research proposals that seek to involve such subjects. AWHC notes that the current law does not require research carried out in NZ to have HDEC approval & that low risk studies do not require approval. However, the threshold for what constitutes low risk must necessarily be much higher when considering research in such vulnerable groups as incompetent adults who cannot weight the risks & benefits for themselves & make informed decisions or advocate for themselves if & when anything goes wrong, & cannot withdraw their consent or withdraw from the research at will.
It must be accepted that, because of the vulnerabilities of incompetent adults & the need to protect them, the timeframes for approval or otherwise of research proposals must necessarily be different from research that involves competent participants. Longer lead-in times must be accepted (by researchers, sponsors such as pharmaceutical companies, & ethics committees) & timelines established to benefit & protect the research subjects rather than research being expedited for the

convenience & benefit of the researcher/s.
AWHC protests in the strongest possible terms the lack of real consultation with the community & patient advocates with regard to proposed softening of the regulations to allow the enrolment of incompetent patients in research. In a letter (7 November 2016) to AWHC by HD Commissioner, Anthony Hill stated that "it is likely that, in addition to inviting written submissions, my Office will organise focus groups and/or public meetings to facilitate discussion of the issues raised by the consultation document. The exact details of the consultation process will be released concurrently with the consultation document". Despite this undertaking AWHC has not seen any further evidence of the intention to do so.
Any proposal to involve vulnerable people in medical experiments without their consent contravenes the Nuremberg Code. Although the Declaration of Helsinki & our own Code of Rights are watered down versions of the Nuremberg Code, they still protect the rights of incompetent adults, albeit with wording that is at times vague & open to interpretation. Any change that would allow or sanction medical experimentation on NZers, especially our most vulnerable citizens, requires more than submissions on a consultation document that has had little media coverage. It is entirely likely that significant portions of the potentially affected sectors of our community & their family/whānau, & the health professionals who care for them, are entirely unaware of the existence of the consultation paper or proposed changes to the Code.
AWHC requests that further consultation to elicit greater community comment & involvement in any changes to the Code & that any changes not be expedited at the expense of our most vulnerable citizens.

Please state your name

Organisation (if applicable)

Auckland Women's Health Council

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.