

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

OFFICE OF THE HEALTH AND DISABILITY COMMISSIONER



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Commissioner's foreword

I conducted a public consultation regarding the application of the Code of Health and Disability Services Consumers' Rights (the Code) to health and disability research involving adult consumers who are unable to consent to their participation in the research. Those consumers might, for example, be unconscious, or have significant cognitive impairments that prevent them from understanding the implications of the decision to participate.

The existing law in New Zealand as set out in Right 7(4) of the Code allows consumers who are unable to give informed consent to be provided with services, including being participants in health or disability research, if to do so is in their "best interests". I consider "best interests" to be the appropriate standard in clinical care when health decisions must be made for people who are unable to make or express decisions themselves, have no one legally entitled to consent on their behalf, and their wishes are not known. However, the best interests standard is less appropriate for research participation. The nature of research is that the outcomes are uncertain, so it is difficult to assess in advance the risks and "key benefits" for the consumer participants.

The submissions my Office received recognised and reflected the complexity of the ethical issues involved. There is a strong imperative to advance medical science, and thus the quality of care. However, consumers who are unable to make informed decisions for themselves are particularly vulnerable to abuses of their rights and interests. The wide range of views expressed by submitters demonstrated the challenge involved in balancing the necessity to protect such vulnerable consumers whilst permitting research that might lead to significant advances in the care we are able to provide to them or to other similar consumers in the future.

I have considered the submissions very carefully and have concluded that the best interests test, although appropriate for decisions to provide treatment to people who cannot give informed consent, is not the right test for research. I have concluded that the test should be more directly focused on the risks and burdens faced by individual participants.

I have concluded that adults who are unable to give informed consent should be research participants only if the research poses no more than minimal risk and no more than minimal burden to them. I consider that there should also be additional protections, including a requirement that health and disability research involving adults who cannot give informed consent cannot proceed unless the research has been reviewed by a specialist ethics committee. In addition, available suitable persons interested in the welfare of the consumer (such as friends and family/whānau) should be able to veto that person's participation in the research without having to justify that decision. I also consider that the prospective participants should be involved in decision-making as much as possible, and that any expression of dissent should be respected and responded to.

I do not intend to consult on the proposed amendments to the Code until after my recommendations on pages 10 to 11 are implemented. I would like to thank those people who have been involved in this process, including the public who made submissions, the expert advisory group, and many others who have shared their views.

Anthony Hill
Health and Disability Commissioner



Executive summary

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Introduction

This review by the Health and Disability Commissioner examines whether changes are needed to the current rules relating to health and disability research involving adults¹ who are unable to give informed consent² to participate in research.

Informed consent is a fundamental requirement before providing health and disability services to any consumer, as set out in Right 7 of the Code of Health and Disability Services Consumers' Rights (the Code). These requirements also apply to any health and disability research that is covered by the Code.

However, there are exceptions to this. When someone is unable to give informed consent, in certain limited circumstances, including that the research will be in the person's "best interests", Right 7(4) of the Code allows the person to be enrolled as a research participant. The "best interests" test does not provide for any consideration of the potential for advances in knowledge that may benefit people other than the participant. Research involving incompetent consumers can lead to advances in the care and treatment available in the future either to those consumers or others with similar conditions. The interest of others is not a relevant factor in New Zealand's current legal framework. "Best interests" in the context of medical research is complicated by the fact that it is difficult to predict accurately to a participant the risks and benefits of the research. The benefits could include a potential improvement in a medical condition, the prevention of further deterioration, and/or the prolongation of life. "Best interests" may also encompass non-medical factors such as emotional and other benefits. (See the discussion on page 33.) It has been argued — particularly by some researchers, academics, and clinicians — that, in the case of research, the "best interests" test has created barriers that mean that some important low-risk research is not legally permissible, potentially depriving some consumers of the benefits of research,

including improved treatments and services for their conditions.

Others have argued that research involving participants who cannot give informed consent should never be permitted, and that doing so breaches the principle of autonomy and risks harming or exploiting vulnerable consumers.

These are complex and challenging issues that involve competing priorities and strongly held values and concerns. The issues involved also go well beyond the Code.

The Health and Disability Commissioner is primarily concerned with promoting and protecting the rights of consumers as set out in the Code, which include both the right to give informed consent (Right 7), and also the right to services of an appropriate standard (Right 4). High quality services require a sound evidence base, which generally necessitates that robust research is undertaken. The central challenge, therefore, has been to find the right balance between protecting vulnerable consumers and allowing research to progress in order to improve the effective delivery of health and disability services to such people. This has been the issue at the heart of this review.

Overall, the review has addressed three key questions:

- 1 Should the Code be amended to enable some research not currently permitted involving adults who are unable to consent, to be carried out, and, in particular, should the "best interests" test apply to research?
- 2 If the Code were to be amended, what other provisions and safeguards should be in place, either in the Code or elsewhere?
- 3 Are there issues that the Commissioner should highlight to other responsible agencies about the overall system for governing and managing health and disability research involving adults unable to consent, including the conditions that must be implemented but are beyond the ambit of the Code?

1 This report relates to health and disability research that is within the jurisdiction of the Health and Disability Commissioner. In this report, "adult" refers to a person aged 18 years or over.

2 For example, when the person is unconscious, or has a severe intellectual disability or an illness such as advanced dementia.

In brief, this review has concluded that some health and disability research with adults unable to consent that is not currently permitted should be allowed, in order to build greater knowledge of certain conditions and to improve treatment and services for groups affected by those conditions. However, this should apply only in limited circumstances, and only with very robust safeguards in place. This would require the “best interests” test in Right 7(4) of the Code to be confined to the provision of treatment and services, and the development of a different test for research, plus additional safeguards. The Commissioner’s preferred option in regard to research is to introduce into the Code a requirement that there should be “no more than minimal foreseeable risk and no more than minimal foreseeable burden to participants”.

Other safeguards are needed. These include comprehensive principles in the Code and elsewhere to underpin health and disability research with adults unable to consent; enhancements to the ethics review and approval processes and governance system for health and disability research with adults unable to consent; and monitoring and evaluation of any changes that are implemented, with a particular focus on outcomes for consumers.

This report sets out the Commissioner’s thinking in detail and how the conclusions were reached, and makes recommendations for next steps. The review makes recommendations for proposed changes to the Code, and safeguards in the wider system that would be required. Any changes to the Code would require further formal public consultation by the Commissioner.

A comprehensive set of principles

The Code is only one part of an overall system, with other legal and ethical parameters contained in the New Zealand Bill of Rights Act (1990) (NZBORA), the Protection of Personal Property and Rights Act 1988 (PPPR Act), National Ethics Advisory Committee (NEAC) guidelines,

Health and Disability Ethics Committees’ (HDECs) Standard Operating Procedures (SOPs), and the United Nations Convention on the Rights of People with Disabilities. There is a need to ensure that different parts of the system work well together, but the first step is to agree on what a comprehensive set of principles ought to be. The principles proposed below relate to study approval and the enrolment of individuals in an approved study. They are intended to ensure that research with adults unable to consent occurs only if there is no other way to answer the research question, that it is directly relevant to the participants’ condition, that it is valuable and likely to advance knowledge, and that individuals are protected from no more than minimal foreseeable risk of harm and no more than minimal foreseeable burden.

No changes are proposed at this time regarding who makes the decision to enrol an individual. The current rules would continue to apply, namely, that a person legally entitled to consent on behalf of the consumer³ would give consent where possible, and otherwise the provider would make the decision (as per Right 7(4) of the Code). Additional safeguards are proposed, however, including the right of “other suitable persons” to veto participation in the research. Of particular concern are consumers who have no person legally entitled to consent on their behalf and no suitable person who could be consulted, for example, a person with severe dementia in an aged residential care facility who has not appointed an enduring power of attorney (EPOA), the Family Court has not appointed a welfare guardian, and the person has no family or friends interested in his or her welfare. These people may be isolated and are extremely vulnerable, and should never be enrolled in research.

Ethics committee approval should be mandatory for health and disability research involving adults unable to consent.

3 For example, a welfare guardian or attorney appointed under an activated enduring power of attorney could consent if the research is not a “medical experiment”.

Table 1: Summary of proposed principles for health and disability research involving people unable to consent

#	Proposed principle	Relates to:
1	Ethics committee approval should be mandatory for health and disability research including adults unable to consent	Individual enrolment
2	The research question must not be able to be answered with alternative participants who can consent, or with an alternative research design that does not involve people unable to consent	Study approval
3	The research must advance knowledge about the condition causing the participants' impairment or its treatment or relevant services	Study approval
4	The research must have scientific merit and social value, and answer a genuine research question	Study approval
5	Where a provider is the decision-maker, any perceived or actual conflicts of interest or potential for coercion arising from the researcher and provider being the same person or closely aligned, must be addressed in the research protocols to the satisfaction of a specialist ethics committee	Study approval
6	Participation in the research would present no more than minimal foreseeable risk and minimal foreseeable burden to research participants	Study approval AND Individual enrolment
6a	If an assessment of the level of risk and burden for any individual participant(s) will not be possible because of the nature of the research, then this must be addressed explicitly during the ethics review and approval process, and there should be auditing and follow-up of the research to the extent determined necessary by the specialist ethics committee. This will apply only in very limited emergency research scenarios	Study approval
7	If there is a person entitled to give consent on behalf of the consumer, that person must give consent where possible	Individual enrolment
7a	If there is no person entitled to consent on behalf of the consumer, the provider should be the decision-maker	Individual enrolment
7b	Where the provider is the decision-maker, other available suitable persons, including authorised representatives (ARs), must be consulted, and they have a right to veto participation in the research at any time for any reason unless the participant regains capability to consent and exercises that right	Individual enrolment

<p>7c If suitable persons cannot be consulted, then:</p> <ul style="list-style-type: none"> • In situations where there is no time to consult with suitable persons, enrolment can proceed (as long as other provisions are met), with a requirement that consultation occur as soon as possible with those persons having the option to veto participation (withdraw if practicable and/or prohibit use of data) at that time, and • In situations where the proposed participant has no suitable persons who could be consulted, that person must not be enrolled in the research study 	<p>Study approval AND Individual enrolment</p>
<p>8 The participant's wishes must be taken into account to the extent possible:</p> <ul style="list-style-type: none"> • Efforts must be made to obtain prior consent or assent • Any known prior objection must be respected • Any indication of dissent must be respected and responded to on an individual basis • If there is reason to believe that participation would be consistent with the person's wishes, that must be complied with 	<p>Individual enrolment</p>
<p>9 If the person regains capacity to consent, or regains some competence to be supported in a decision, where practicable, the person must be given the opportunity to consent or refuse consent to continued participation in the research and/or for the use of any data already collected</p>	<p>Individual enrolment</p>

Ethics review and approval processes and governance

The research ethics review and approval system is a critical safeguard for protecting research participants. It is proposed that ethics committee approval should be mandatory for all health and disability research involving adults unable to consent.

Furthermore, it is recommended that there be a specialist ethics committee to oversee all health and disability research involving adults unable to consent that is adequately resourced to commission independent peer review and risk assessment as required. This committee should also be resourced to carry out auditing, monitoring, and follow-up of these research studies, particularly studies where participants may have been enrolled without consultation with suitable persons who are interested in their welfare, or without an individual risk assessment.

Monitoring and evaluation of any changes

A further safeguard is that there should be monitoring and evaluation of any changes made to the rules relating to research involving adults unable to consent. A focus of any such monitoring and evaluation should be the outcomes for consumers, and in particular whether the protections for consumers are sufficiently robust once implemented.

Recommendations

It is recommended that the Minister of Health:

- 1** **Note** the Health and Disability Commissioner’s conclusion that some health and disability research not currently permitted involving adults unable to consent should be allowed in order to build greater knowledge of certain conditions, treatment, and services, but only in limited circumstances and with robust safeguards.

- 2** **Note** that allowing some research to proceed that is currently not permitted would require a different regime for research, while Right 7(4) of the Code of Health and Disability Services Consumers’ Rights would continue to apply to treatment and services.

- 3** **Note** the Health and Disability Commissioner’s view that, subject to other safeguards being in place, health and disability research involving adults unable to consent should be permitted if it entails “no more than minimal foreseeable risk and no more than minimal foreseeable burden” to participants.

- 4** **Note** that additional safeguards to protect these very vulnerable groups of consumers should be introduced, including:

 - a. A comprehensive set of principles with an appropriate regulatory framework to underpin the legal and ethical settings for health and disability research involving adults unable to consent (see Recommendation 5);
 - b. A specialised ethics review and approval process and enhanced governance system in relation to health and disability research involving adults unable to consent (see Recommendation 6);
 - c. Monitoring and evaluation of any changes to the legal and ethical framework, systems, and processes relating to health and disability research with adults unable to consent, with a particular focus on outcomes for participants.

5

Note that the principles referred to in Recommendation 4(a) cover both the approval of research studies by ethics committees, requiring updating of the National Ethics Advisory Committee (NEAC) guidelines and Standard Operating Procedures, and decisions about enrolling an individual in a study, requiring amendments to the Code.

The principles that should be applied by ethics committees when determining whether to approve a study including adult participants who are unable to consent should include:

- a. Such research should be permitted only when the research question cannot be answered without involving adults unable to consent;
- b. Such research should be permitted only when the purpose of the research is to advance knowledge about the condition causing the participants' impairment or its treatment or relevant services;
- c. Such research should be scientifically robust, worthwhile (have social value), and aim to answer a genuine research question;
- d. Such research should involve no more than minimal foreseeable risk and no more than minimal foreseeable burden to participants;
- e. Where the provider is the decision-maker with regard to enrolment of participants, the management of any perceived or actual conflicts of interest arising from the researcher and the provider being the same person or closely aligned should be actively addressed in research protocols to the satisfaction of the ethics committee.

6

Note that the amendments to the ethics review and approval processes and governance system referred to in Recommendation 4(b) include:

- a. That no health and disability research with adult participants who are unable to consent should take place unless the research has received the approval of an ethics committee;
- b. Amending pathways to enable all health and disability research studies involving adults unable to consent to be considered by an ethics committee;
- c. Clear guidance being developed about defining and assessing minimal foreseeable risk and minimal foreseeable burden;
- d. A specialist ethics committee being established with responsibility for reviewing all health and disability research involving adults unable to consent that would:
 - i. Have the necessary expertise to evaluate risks and other considerations, and/or have the resources to commission its own peer review and risk assessment;
 - ii. Be resourced to oversee auditing and follow-up of approved research studies;
 - iii. Play a role in monitoring and oversight of approved research studies and the outcomes for participants.

7

Note that the principles that should be incorporated in the Code include:

- a. A consumer who is unable to give informed consent may only be enrolled in health and disability research that has been approved by an ethics committee;
- b. A consumer who is unable to give informed consent may be enrolled in health and disability research only if the research will involve no more than minimal foreseeable risk and no more than minimal foreseeable burden to that consumer;
- c. The consumer's known wishes should be taken into account as practicable;
- d. Any indications of dissent by the consumer should be respected and responded to on an individual basis;
- e. If the research participant regains capacity to consent, or some capacity to be supported in a decision, where practicable that consumer must, as soon as possible, be given the opportunity to give or decline informed consent to continued participation in the research, and/or to the use of data about that consumer that has already been collected;
- f. The decision about enrolling such a consumer in an approved research study should be made by a person legally entitled to consent on behalf of the consumer, where possible;
- g. Where there is no person legally entitled to consent on behalf of the consumer, the decision-maker about enrolling an individual should be the provider;
- h. Where the provider is the decision-maker:
 - i. Available suitable persons interested in the consumer's welfare must be consulted (as now required under Right 7(4)), and those suitable persons should have the right to veto participation in the research at any time for any reason;
 - ii. If the consumer has no suitable person interested in his or her welfare to consult, he or she should not be enrolled in research;
 - iii. If because of the nature of the research, there is no time to identify whether there are suitable persons who could be consulted or to consult them, the consumer may be enrolled in the research, but suitable persons must be consulted as soon as possible and have the right to veto further participation and to withdraw the data collected if practicable.

8

Agree to the intent of the changes to the Code as set out in Recommendation 7 prior to HDC undertaking public consultation on the proposed amendments to the Code.

9

Direct the Ministry of Health to update those aspects of the NEAC guidelines and Standard Operating Procedures that can be amended prior to any changes to the Code, in line with Recommendations 4, 5 and 6.

10

Direct the Ministry of Health to report back to you on how to best give effect to the remaining safeguards outlined in Recommendation 4.

11

Note that following implementation of appropriate safeguards by the Ministry of Health and public consultation on the proposed amendments to the Code, I will seek your agreement to make any changes to the Code to give effect to the new regime for health and disability research involving adult participants who are unable to give informed consent to their participation.



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Focus of the review

The Health and Disability Commissioner has undertaken a review focused on the law regarding health and disability research with adult⁴ participants who are unable to give informed consent to participate. People who are unable to consent include consumers who are unconscious when the research is conducted (e.g., in a coma), or consumers with significant cognitive impairments (e.g., advanced dementia or significant intellectual disability) who are unable to give informed consent even with special assistance.

It is a fundamental legal requirement that consumers must provide informed consent before receiving health and disability services, as set out in Right 7 of the Code. This also extends to occasions where a consumer is participating in, or it is proposed that a consumer participate in, health and disability research (Right 9). In certain circumstances, it is appropriate and lawful to provide services to a consumer without consent, as set out in Right 7(4), the common law, and legislation.⁵ Critical amongst these circumstances is Right 7(4)(a), which requires that it must be in the consumer's "best interests" to provide the services (which includes being enrolled as a research participant).

Right 7(4) is an **exception** or defence for providers to the general right that consumers must give informed consent before services are provided.

The issue is whether the provisions in the Code that are clearly appropriate for treatment and services are also appropriate for research.

It has been argued that Right 7(4) has resulted in barriers to potentially valuable research being able to be carried out, owing to the difficulty of demonstrating that participation in research would be in the participant's "best interests". "Best interests" is not defined in the Code, although attempts to define the expression have been made in other jurisdictions.⁶ It requires the decision-maker to strike a balance between the sum of the certain and possible gains against the sum of the certain and possible losses, and only if the account is in relatively significant credit will the decision be in the person's best interests.

It has been argued that this test prevents research that might provide valuable information about the conditions that cause consumers to lack or lose capacity, and about the diagnosis, treatment, care, and needs of such consumers, and that cannot be gained through research with consumers who can consent.

4 This review has focused only on adults who are unable to consent. In this context, an adult is a person aged 18 years or over.

5 For example, the Mental Health (Compulsory Assessment and Treatment) Act 1992.

6 For example, the UK Mental Capacity Act 2005. Section 4 sets out the "best interests" checklist, which tells decision-makers what they have to think about when making "best interests" decisions. They must consider the person's past and present wishes and feelings, values and beliefs. They must — so far as practicable and appropriate — consult with others engaged in caring for that person or interested in the person's welfare. Having followed these steps and taken these matters into account, the person making the decision about best interests must employ what the Court has described as a "balance sheet" approach, which means weighing the likely advantages for the person against the likely disadvantages. Only if the "account" is "relatively significantly in credit", will the intervention be in the person's best interests. The "balance sheet" was developed in *Re A (Medical Treatment: Male Sterilisation)* [2000] 1 FLR 549.

Others have argued that such research is unethical and could amount to exploitation of vulnerable people, and that it is too risky to consider the introduction of a different test for research.

In this current review, it was decided not to focus only on the “best interests” clause in Right 7(4), but to take a wider system-level approach and to consider the Code within a broader context. The review began, therefore, with a broad scope, and originally set out to answer two main questions:

- Are New Zealand’s current laws regarding non-consensual research appropriate?
- If not, how should they be amended?⁷

The public consultation document asked a range of questions about legal and ethical issues relating to research with adults unable to consent. The intention was to explore public views about a broad range of relevant issues, in order to answer the questions above.

The responses from submitters and the experts consulted were, not surprisingly, complex, and went far beyond the Code. They covered more than the topics included in the consultation document. To address all of these issues would require an even larger exercise with involvement from several other agencies. While the Health and Disability Commissioner may express a view on these issues, he is not best placed to carry out a comprehensive review and offer firm recommendations on all of them. At the same time, it was also difficult to look at issues relating to the Code in isolation from these wider issues. These have been amongst the key challenges in carrying out this review.

Despite this complexity, and the need to pay attention to a range of wider system issues, the core issues came through repeatedly in the submissions and in the discussions we held with a variety of individuals and groups throughout the review. These were:

- 1 Should the Code be amended to enable some research to be carried out that is not currently permitted involving adults unable to consent, and, in particular, should the “best interests” test be amended in regard to research?
- 2 If so, what other provisions and safeguards should be in place, either in the Code or elsewhere?

The fundamental issue sitting behind this review has been how to determine the appropriate balance between ensuring protection for consumers who, unlike other potential research participants, are unable to weigh the risks, benefits (to themselves or to others), and burdens of being involved in research and make an informed decision about whether or not to participate, whilst also enabling health and disability research that might enhance knowledge of particular conditions and lead to improvements in health and disability treatments and services. It is this balance that is at the heart of the problem, and it is a question with no easy answer.

This report sets out the Commissioner’s thinking and direction of travel. It proposes changes to the Code that will require further public consultation.⁸

7 HDC Consultation Document: “Health and Disability Research involving adult participants who are unable to provide informed consent”, page 2.

8 This would be required under section 22(1) of the Health and Disability Commissioner Act (1994).

Overview of the current regulatory and ethics framework in NZ

The Code is only one part of an overall system, with other legal and ethical parameters contained in the New Zealand Bill of Rights Act (1990) (NZBORA), the Protection of Personal Property and Rights Act 1988 (PPPR Act), National Ethics Advisory Committee (NEAC) guidelines, and Health and Disability Ethics Committees' (HDECs) Standard Operating Procedures (SOPs).

NZBORA

NZBORA provides that every person has the right not to be subjected to “medical or scientific experimentation” without that person’s consent, and everyone has the right to refuse to undergo any medical treatment.⁹

PPPR Act

A person who lacks capacity to make decisions on his or her own behalf may have a welfare guardian appointed by the Family Court with the power to make decisions about the person’s personal care and welfare.¹⁰ Alternatively, while still able to do so, a person may have appointed someone to make such decisions on his or her behalf should the capacity to make such decisions be lost in the future. The person who is appointed is authorised to act by an activated enduring power of attorney (EPOA) for personal care and welfare.

The first and paramount consideration of a welfare guardian or EPOA (the Authorised Representative (AR)) is the promotion and protection of the welfare and best interests of the person who is unable to make his or her own decisions (s 18(3)).

Section 18(1)(f) of the PPPR Act provides that an AR may consent to the person’s participation in a “medical experiment” only if the experiment is conducted for the purpose of saving the consumer’s life or preventing serious damage to the person’s health.

The terms “medical experiment” in the PPPR Act and “medical or scientific experimentation” in the NZBORA have not been considered by the New Zealand courts, and are not defined in the legislation. However, some health and disability research is unlikely to be considered a medical experiment, e.g., observational research on types of caregiving for people with advanced dementia. If the research is not a medical experiment, then the AR can consent on behalf of the person if the AR is satisfied that participation would promote and protect the person’s welfare and best interests.

The Code of Health and Disability Services Consumers’ Rights

Right 7 of the Code provides that services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of the Code provides otherwise. The Code provides that all consumers must be presumed to be competent to make informed choices and give informed consent, unless there are reasonable grounds for believing that they are not competent.¹¹ Consumers with diminished competence still have the right to make informed choices and give informed consent to the extent appropriate to their level of competence.¹²

Right 9 provides that the rights in the Code extend to those occasions when a consumer is participating in research, or it is proposed that a consumer participate in research.

9 NZBORA sections 10 and 11.

10 The Court may do so only if the person is aged 18 years or over, unless the person is or has been married, in a civil union, or in a de facto relationship. However, a welfare guardian can be appointed for a younger person who has no parent or guardian alive or in regular contact with the person. PPPR Act sections 6(2) and 12(3).

11 Right 7(2).

12 Right 7(3).

If there is no person entitled to give consent on a consumer's behalf, the consumer who cannot give informed consent may not be a research subject unless the criteria in Right 7(4) of the Code are satisfied.

Right 7(4) states that if a consumer is not competent to make an informed choice and give informed consent and no person entitled to consent on behalf of the consumer is available, a provider may provide services to that consumer, including enrolling the consumer in a research study, where:

- it is in the best interests of the consumer; and
- reasonable steps have been taken to ascertain the views of the consumer; and
- either —
 - if the consumer's views have been ascertained and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or —
 - if the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.

Ethics guidelines and committees

Ethics review and approval of proposed research studies are a key part of the system, and act as a critical safeguard for protecting consumers. As part of this process, a researcher must demonstrate that the proposed study would comply with relevant ethics guidelines and the law, including the Code.

Ethical guidelines for health and disability research are developed by the National Ethics Advisory Committee (NEAC) for both interventional and observational studies.¹³ Health and disability research is primarily reviewed by one of four Health and Disability Ethics Committees (HDECs). However, some health and disability research, e.g., some academic research, may be reviewed by Institutional Ethics Committees (IECs) rather than HDECs.

The HDEC SOPs¹⁴ set out the role, scope, coverage, and processes for HDECs, and their reviews are carried out according to NEAC guidelines.

The NEAC guidelines and HDEC SOPs are currently being reviewed by the Ministry of Health.¹⁵

United Nations Convention on the Rights of People with Disabilities

The United Nations Convention on the Rights of Persons with Disabilities (CRPD) established a new paradigm of supported decision-making, rather than guardianship or substituted decision-making, for people with intellectual disability. Article 12 of the CRPD guarantees every person's right to legal capacity — to make her/his own decisions and have those decisions legally recognised — and specifically requires governments to provide people with intellectual disability the supports they may need to exercise legal capacity.

In carrying out this review we have been mindful of the provisions in the CRPD and the need to support consumers to make their own decisions, and to respect their will and preferences to the fullest extent possible.

13 <https://neac.health.govt.nz/home>

14 <https://ethics.health.govt.nz/operating-procedures>

15 See <https://neac.health.govt.nz/consultations>



Section 2:

The review

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Process — What we did

To inform HDC’s thinking on this subject, we reviewed guidelines and legislation from other countries, reviewed key academic articles, and were briefed by experts. An Expert Advisory Group was appointed to advise and assist the Commissioner in relation to the review. All these resources contributed to the development of a consultation document titled “Health and disability research involving adult participants who are unable to provide informed consent”¹⁶ and an online submission form. The consultation document and submission form were translated into “easy-read” format. Both formats were accessible on the HDC website and in hard copy.

People who wished to make a submission could either complete the submission form on-line or send their submission to HDC in hard copy. The submission form asked a number of questions, but respondents could also respond in general terms, rather than answer the specific questions.

To begin engaging with the public, everyone on HDC’s mailing list was sent the consultation document and submission form — 306 individuals, groups, or institutions were contacted in this way. A wide range of government and non-government organisations was asked to publicise the consultation. Following the publication of the consultation document, a number of stakeholders were consulted, including:

- People First
- Disabled Persons Assembly
- HDC’s Consumer Advisory Group
- Capital and Coast District Health Board Research Advisory Group — Māori

- Ministry of Health
- The Ministry of Health’s Consumer Consortium
- HDEC Chairs
- Health Research Council Ethics Committee
- Alzheimers New Zealand
- Age Concern
- University of Otago Bioethics Centre

We received 156 submissions from a variety of groups and individuals. Twenty-four submissions used the “easy-read” form, either on-line or by post, 106 used the standard template, and 26 did not use either template to write their submissions. We carried out a thematic analysis to identify themes for each question, as well as cross-cutting themes. Graphs were produced for questions that had asked yes/no questions with simple descriptive data. The summary of this analysis can be found in the companion document “Summary of Submissions”.¹⁷

We used this information to develop initial options, and gathered further information on particular issues that arose, including further literature review, an OIA request to the Ministry of Health, and further discussions with experts. We held several meetings with our Expert Advisory Group, and met or video-conferenced with other New Zealand and international experts to test our thinking. We also briefed HDC’s Consumer Advisory Group on the direction of the Commissioner’s thinking, to seek their feedback, and met again with the Ministry of Health and the Chairs of the Health and Disability Ethics Committees.

¹⁶ See: <https://www.hdc.org.nz/your-rights/about-the-code/right-7-4-consultation/>

¹⁷ See: <https://www.hdc.org.nz/media/4960/summary-of-submissions.pdf>

Caveats

Caution is needed in interpreting the figures from the graphs, as the analysis of submissions showed that people interpreted the questions very differently. Analysis of the statistics alongside the comments also showed that at times a “yes” response was essentially the same as a “no” response. An example is Question 1.1, which asked, “Do you believe research should ever be allowed to proceed with adult participants who are unable to consent?” Most people qualified their answer in some way to discuss safeguards that should be in place, that is, “Yes, but only if there are safeguards”, and “No, unless there are safeguards”. Thus, simply looking at the figures could be misleading.

It should also be remembered that this was a consultation process, and we cannot say how representative the responses are. For these reasons, in this report we have not cited the figures from the submissions, although they are available in the separate “Summary of Submissions” document. Nevertheless, the submissions provide rich information and have been invaluable for informing our thinking.

We are grateful for all the input we have had and the efforts people have made to help us to unravel these very complex questions. In particular, we are grateful to our Expert Advisory Group members (see Appendix 1 for biographies), who have contributed significantly over many months:

- Ms Jane Bawden (Chair)
- Dr Colin McArthur
- Professor Alan Merry
- Dr Brigit Mirfin-Veitch
- Dr Jeanne Snelling
- Ms Teresa Wall

Approach to the report

This section briefly outlines the general approach taken to writing up this report, and introduces some of the key concepts used in the analysis.

The Health and Disability Commissioner has a mandate to make recommendations for changes to the Act and Code, and also has the role of making suggestions and/or reporting to the Minister or anyone else on the need for, or desirability of, action to protect the rights of health or disability services consumers. The Introduction above notes that this report makes recommendations about changes to the Code, and signals other necessary provisions and safeguards. The report does not suggest specific wording changes to the Code, but focuses instead on the key principles and ideas. More detailed drafting would take place prior to any formal consultation on proposed Code changes.

A key challenge to developing a generalised set of rules or principles for research involving adults unable to consent is the variety of circumstances covered, such as research with people who have a progressive illness (such as dementia), people who have a serious or severe intellectual or learning disability, and people in an emergency situation (due to, for example, head trauma, sepsis, cardiac arrest, and stroke), some of whom may regain capacity at some point. This variation means that what might work well in some situations is less likely to work well in others, with particular challenges relating to the timeframe of the research (e.g., emergency research where decisions about enrolling a person in a research study must be made quickly, often with no time to consult with other people).

This has created challenges for constructing a “one size fits all” approach and, in parts of the report, options are given for alternative approaches depending on the circumstances. The variety of types of health and disability research also needs to be factored in. This report does not specifically address issues of relevance to particular cultural or ethnic groups.

Our approach has been not to make assumptions about how particular groups might think about these issues. Māori advisors to whom we spoke suggested that making blanket assumptions about how Māori would view participating in research is inappropriate and could result in additional barriers for Māori in participating in research. Research protocols should say how cultural needs will be met, but not make presumptions about what the specific needs are for individuals or whānau. The system and practices should be sufficiently flexible to allow different needs and preferences to be met. Thus, this report has not made any particular assumptions about what will work for different cultural groups.

During the review, different regulatory and non-regulatory instruments and options that could be used to give effect to the principles for a regime for research with adults unable to consent were considered. Key considerations are what amendments might be made to the Code, what is captured in the NEAC guidelines, and whether there should be new stand-alone legislation regarding mental incapacity, such as the England and Wales Mental Capacity Act, or the Adults with Incapacity (Scotland) Act.

Submitters also expressed many views about whether the same laws should apply to all health and disability research, and the general question of consistency and coordination. However, this report focuses on potential changes to the Code, and other necessary safeguards in the wider system.

Finally, we have approached the issues around research with adults unable to consent by being explicit that there is a two-step decision-making process to be considered: the approval of a research study to allow it to proceed; and the enrolment of a particular individual in that study.

These are distinct steps with different decision-makers, but are often conflated. This review argues that the two steps must be integrated into a cohesive system, but that they must also be clearly distinguished — both steps are imperative, but approval of a study that has considered issues of risks, burdens, and benefits at a population level does not necessarily lead to conclusions about whether any particular individual should be enrolled in the study. Issues of study approval and individual enrolment will be referred to throughout the report.

The following section sets out the results of the review and discusses the issues and options considered. It begins with an overview of problems identified with the current regime, before addressing the first key question of whether the Code should be amended, and what alternative options for the “best interests” test there might be.

It then considers the second question, namely the other provisions and safeguards that would need to be in place should the “best interests” test be amended. This takes the form of a comprehensive set of principles that relates to both study approval and individual enrolment, plus suggestions for enhancing the ethics review and approval process for research involving adults unable to consent. Monitoring and evaluation of any changes are also recommended.

We refer to comments made by submitters and others consulted throughout the review in order to illustrate key points, but the full summary of submissions is contained in the separate document.

The report concludes with a summary of recommendations and proposals for next steps.





Section 3:

Results and discussion

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Issues identified in the current regime

The review began by considering the presenting problem that had been identified by some researchers and other commentators, namely that some ethically sound research that could be of benefit to groups of people who are particularly vulnerable is not able to be undertaken because of the “best interests” provision in Right 7(4) of the Code. This is said to have implications for improvements in understanding of certain conditions, and in healthcare and services related to those conditions. The best interests test does not provide for any consideration of the potential for advances in knowledge that may benefit people other than the participant. Research involving incompetent consumers can lead to advances in the care and treatment available in the future either to those consumers or others with similar conditions. The interest of others is not a relevant factor in New Zealand’s current legal framework.

“Best interests” in the context of medical research is complicated by the fact that it is difficult to predict accurately to a participant the risks and benefits of the research. The benefits could include a potential improvement in a medical condition, the prevention of further deterioration, and/or the prolongation of life. Best interests may also encompass non-medical factors such as emotional and other benefits. (See the discussion on page 33.)

Submitters discussed these issues in detail. There are some who hold strong views that research with adults unable to consent should never be permitted and is never ethically acceptable:

I do not think any adult has the right to consent for another adult.

Many other submitters, however, highlighted the importance of being able to undertake research with these groups, and described the problem as being how to get the balance right between enabling research that may enable improvements in health and disability services, and ensuring the right level of protection for people who, unlike other potential research participants, are unable to weigh the risks, benefits (to themselves

or to others), and burdens of being involved in research, and to make an informed decision about whether or not to participate:

We believe the overarching ethical framework for research with adults unable to consent should be “promoting the interests of vulnerable consumers”. This approach would acknowledge the benefits of medical knowledge to consumers as a group, the risks of non-evidence based clinical care (where evidence is weak or lacking) and the risks and potential benefits for individual consumers participating in a research study. The research ethics framework should facilitate access to the benefits of medical knowledge while preventing undue harm. We need to aim for balance and avoid a myopic focus on risk.

As discussed earlier, the key legislative barrier to research with adults unable to consent is that researchers must demonstrate that their research is lawful, which includes complying with Right 7(4) of the Code. Compliance with Right 7(4) requires that participation in the research is in the “best interests” of individual participants, and compliance is required at both the ethics committee approval stage and when enrolling individual participants. Some submitters argued that this is an unreasonable and inappropriate test for research, and that it sets a threshold that is difficult, if not impossible, to meet. The reasons for this are discussed in more detail below.

A further issue is that s 18(1)(f) of the PPPR Act provides that no welfare guardian or attorney (the AR) shall have power to “consent to that person’s taking part in any medical experiment other than one to be conducted for the purpose of saving that person’s life or of preventing serious damage to that person’s health”. ARs could consent to someone participating in health and disability research that does not involve a medical experiment, if this would promote and protect the welfare and best interests of the person for whom they are acting (s 18(3)).

It is logical to conclude that the current legislation could act as a barrier, since the law is clear that there must be informed consent before participating in health and disability research, with Right 7(4) providing an exception to this

in limited circumstances. How many studies might otherwise be carried out is an impossible question to answer. It is likewise difficult to quantify the **impact** of research **not** being done.

HDECs do receive proposals from researchers for research involving adults unable to consent, and at least some of these have been approved. The Ministry of Health estimates that between 2006 and July 2012, there were around 30 approved non-consensual studies. Between July 2012 and October 2016 there were about 40 studies approved and 5–6 declined. These estimates are likely to be conservative.¹⁸

However, there is no way to measure how many possible studies have **not** been submitted to an ethics committee because of the difficulties of demonstrating “best interests”.

In terms of the impact of such research not being carried out, the HDEC Chairs submitted that they have heard from many researchers, particularly those in intensive care, intellectual disability, and psychogeriatric settings, who report that Right 7(4) is preventing valuable and ethical research involving participants who are unable to consent, because it cannot meet the “best interests” test. They suggested that this is restricting the development of services for consumers in those groups. This was also the view expressed in a number of submissions in this review.

The consultation document included several case studies setting out different examples of research involving adults unable to consent, all of which would be currently unlawful. Many submitters felt that at least some of them were ethical, should be permitted, and they would personally be willing to participate in them — in particular, Case Study A: Observational study measuring clearance of antibiotics during dialysis, and Case Study B: Clinical trial comparing two products used following neurosurgery. In others, such as Case Study D: Clinical trial regarding use of adrenaline following cardiac arrest, results were more mixed, and some, such as Case Study E: Clinical trial of drug for people with Down Syndrome, were clearly not supported.

The evidence is therefore somewhat anecdotal, but it is difficult to see how it could be anything else.

A number of submitters raised concerns that these types of studies were being approved based on researchers having asserted that the “inclusion benefits” met the “best interests” test. Some submitters questioned whether inclusion benefits should be used as justification for either study approval or enrolment of an individual who cannot consent.

Concerns were also raised that aspects of the health and disability ethics review and approval process — a key safeguard in the system — need to be strengthened. Some of the issues raised were in the context of perceived problems in the system currently; and some were in the context of what additional safeguards would be needed should there be a change to the Code that would allow currently prohibited research to occur.

There have been few complaints to the Health and Disability Commissioner about research with consumers unable to consent. Nor have we been shown any evidence that inappropriate research has been carried out, or that consumers have been inappropriately enrolled in research and/or harmed as a result. A lack of complaints is not necessarily evidence that there is no problem — and there are many reasons why people may not complain about research — but it does mean there is a lack of information regarding adequacy of protection.

However, while these issues cannot be quantified, the views of submitters and our expert advisors suggest that they should not be ignored. In summary, the review points to a complex set of problems, not all of which stem from Right 7(4). The need to weigh up the interests of individuals and wider society is the fundamental challenge in deciding whether to allow more research with adults unable to consent. The following section sets out the Commissioner’s views on whether there should be a change to the Code, and what such a change might look like.

18 Email from Philippa Bascand, Manager Ethics Committees, Ministry of Health, 6 October 2016.

Should some research involving adults unable to consent that is not currently allowed under Right 7(4) be permitted, and should the Code be amended? (Question 1)

Arguments for and against allowing some research with adults who cannot consent that is currently not permitted

During the review, different views were expressed about what weight the above issues should be given. Protection of consumers was seen as crucial, but there were differences of opinion about whether the need to do research that is currently prohibited outweighs other considerations. There was no clear pattern amongst submitters in respect of this question. Whilst researchers and clinicians tended to argue that at least some such research would be desirable (albeit with safeguards), consumers expressed a wide range of views about the issue. Some said it was exploitative and too risky, but others wanted people who lacked the capacity to give informed consent to benefit from the advances in knowledge that research could bring.

Some people felt that no research should ever be allowed; others felt it depended in part on the type of research:

Whether such research should be permitted would depend entirely on the nature of the research ... 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 ...

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.

Overall, most people considered that some such research should be permitted but only in limited circumstances and with strong safeguards.

The arguments against amending the current rules to allow some research that is currently not permitted can be summarised as:

- Autonomy and the right of the individual to choose whether or not to participate in research is paramount and trumps all other considerations;
- Fears of exploitation, abuse, and harm of vulnerable people;
- The person has no say over whether or not to accept the risk of harm (linking to autonomy);
- It is unfair or inequitable that adults who cannot consent may find themselves enrolled in research, whereas people who do have the capacity to consent are not required or obligated to participate in research.

The arguments in favour of allowing some currently prohibited research can be summarised as:

- Sometimes research with adults who cannot consent is the only way to build an evidence base to support the development of better treatment and services for consumers with the conditions that cause the proposed participants to be unable to consent;
- Without research, cohorts of consumers are disadvantaged, as the quality and effectiveness of care delivered to them is eroded due to a poorer evidence base, and they become “therapeutic orphans”. Some submitters framed this as a “rights” issue.

Several people noted that constantly striving to improve services is a feature of robust health and disability systems. It was stated that good research and a sound evidence base underpin a high quality health and disability system and are what make improvements possible. It is not always well understood how important this is.

Gillett, for example, comments that it is important to understand that it is common in medicine for standard practices and treatments to “outstrip the best evidence for their efficacy in the conditions they are being used for¹⁹”. However, improvements cannot happen without being able to do robust research.

One expert pointed out that there will be risks for consumers either from research or from services — it is all about where the risk lies, whether the risk to individuals is justified by wider social benefit, and whether it is considered more acceptable for risks to lie in research or treatment. Likewise, one submitter stated:

It's illogical to allow clinicians to give a treatment that could be harmful, but not to allow them to test that treatment.

There is no right answer. Experts on this issue to whom we spoke described this as a complex problem on which there is no consensus in the world of research ethics. There are two primary reasons why the question is so challenging.

First, the ethical dilemma is that research by definition is not primarily about providing therapeutic benefit to an individual, but about building a knowledge base through answering research questions and testing hypotheses for the benefit of people in the future.²⁰ There may be times when research does have the potential to benefit an individual (and this may be a motivation for the individual to participate) but this is not its primary purpose. In research, the burden and risk of harm (to the subject) and the expected accrual of benefit (to future patients) are dissociated from each other.²¹ The core issue, then, is how to “involve humans in research for the benefit of future patients and society as a whole, without violating the basic rights of the individual”.²² As one expert put it to us, “What claim can society make on individuals for wider benefit?”

When research includes as participants people who are unable to give informed consent, the ethical challenges are greater because the participants are not able to weigh up the risks and benefits to decide whether to participate.

This is not a question where gathering and assessing evidence leads to the “right” answer. Rather, it is inherently a bioethical problem that requires weighing up different priorities and values and settling on an appropriate balance between competing concerns.

While concerns about risks of harm and exploitation can be mitigated, the question remains whether it is “fair” to compel individuals who are unable to consent to participate in research when people with capacity are not similarly required to be involved. But doing nothing is also problematic because of the impact on improvements to services for these vulnerable groups of consumers, and thus the potential disadvantage to them.

The complexity of the issue was perhaps reflected in the relatively low response rate to the question in the consultation document of whether the best interests test strikes an appropriate balance between protecting the rights of consumers and allowing research to proceed, with over one third of submitters not responding. Of those who responded, most felt that it did not strike an appropriate balance, and felt that it created a barrier to research that could lead to improvements in treatment and services for these groups.

The review has weighed up the question of whether some health and disability research involving adults unable to consent that is not currently permitted under Right 7(4) should be allowed, taking into account two things that are of critical concern to the Commissioner: the right of consumers to give informed consent (Right 7), and the right to receive services of an appropriate standard (Right 4).

19 Gillett, G. (2014), “ICU research ethics and trials on unconscious patients”, <https://www.ncbi.nlm.nih.gov/pubmed/25943602>.

20 Berger, J. (2011), “Is best interests a relevant decision-making standard for enrolling non-capacitated subjects into clinical research?”. *Journal of Medical Ethics*, 37: 45–49. Doi:10.1136/jme.2010.037515.

21 Berger, *ibid*.

22 Berg, R.M.G., Moller, K. and Rossel, P.J.H (2013), “An ethical analysis of proxy and waiver of consent in critical care research”. *Acta Anaesthetologica Scandinavica*, 57: 408–416. Doi:10.1111/aas.12083.

Consumers have the right to receive services that are consistent with their needs (Right 4(3)), and that minimise potential harm and optimise their quality of life (Right 4(4)). This requires the effective functioning of the wider health and disability system, including providing services that are evidence-based.

The argument was made during the review that the risks of some research are low, and that:

A research ethics paradigm that focuses only on the dangers of research [is] distorted.

There is a need to understand more about conditions that result in a loss of capacity, and effective ways to treat them and/or to deliver health and disability services to people with such conditions. At times, this requires involving those people in research — otherwise, we deprive cohorts of consumers of the benefits of research. The ideal outcome of this review is to find a way to allow potentially valuable, low risk research while maintaining or strengthening protections for vulnerable consumers. The bottom line is that protections must not be weakened.

In the following section, we consider the appropriateness of the “best interests” test in relation to research, and alternatives to it.

Risks, burden, and benefits — why “best interests” is the “wrong” test for research

If we accept that some research involving adults unable to consent is desirable, it is necessary to understand why the “best interests” test is problematic, and then consider what it should be replaced with.

It is necessary to have some kind of test to weigh the risks, burdens, and benefits to decide whether such research should be permitted, and/or whether an individual should be enrolled in it. Different jurisdictions use different tests to define and assess the acceptable levels of risk of harm, potential benefit, and burden. In New Zealand,

“best interests” is the key legal test for determining advantages and disadvantages to research participants who are unable to consent. Elsewhere, “best interests” has also been widely acknowledged as the appropriate ethical norm that forms the basis for enrolling individuals who cannot consent in research.²³

Some submitters said that the “best interests” test sets a threshold that is too high, resulting in barriers to research. During the review, it was also suggested that it is not that the test is too difficult to meet, but that it is the **wrong** test for research. Primarily this is because the main purpose of research is to develop knowledge for the benefit of others (e.g., through more effective treatment and services), not the research participants and, by definition, individual benefits are speculative at the time the research commences. This has also been discussed in the literature. Berger, for example, argues that:

It is difficult, if not often impossible, to determine that enrolment into research offers the highest net benefit because, among other reasons, most clinical research is intended either to demonstrate absence of harm (early phase trials) or to establish benefit (later phase trials), and because research is never primarily intended to benefit its subjects (p45).²⁴

He argues that there is no functional definition of “best interests”, noting that it requires a complex determination of net benefit to decide on the action that is likely to produce the greatest balance of benefit over harm for the individual — something that is almost impossible to do.

A number of submitters also commented that the test was unreasonable for decisions about research participation (although not for services, particularly emergency treatment). One questioned its logic, saying:

If you thought there was a benefit, why do you need to do research?

23 Berger, J. (2011), “Is best interests a relevant decision making standard for enrolling non-capacitated subjects into clinical research?”. *Journal of Medical Ethics*, 37: 45–49.

24 See Berger, *ibid.*

Thus, if the goal is to create a regime where it is possible to do some research with adults unable to consent, then “best interests” is the wrong test.

Another concern raised was that some researchers argue that research is in the best interests of participants because there are inclusion benefits from research. These are the benefits that are said to come from participation in research itself, and may include such things as additional monitoring or greater levels of interactions between families and clinicians.

Some experts spoken to in the review commented that they found inclusion benefits to be an unconvincing argument, with one saying:

If research participation is really so beneficial, we would have droves of people with capacity demanding to be in research.

Manning suggests that even if there is scientific evidence of inclusion benefits, using this as a basis for carrying out research with adults unable to consent is “misconceived”, noting that:

The inclusion benefit is a secondary benefit of being involved in the research and can never be the only justification for being in the best interests of patients. Any such benefit to a particular patient is uncertain, and, even if it eventuates, would have to outweigh the study’s risks and burdens. [Moreover,] researchers do not rely on it to establish the best interests of competent patients justifying their inclusion in clinical research.²⁵

The types of things that are typically said to constitute inclusion benefits (e.g., greater monitoring) could just as easily be seen as a means of mitigating the additional risk of being in the research, rather than an actual benefit. It has also been suggested to us that “more care” is not an unambiguously good thing but is very context dependent. Furthermore, if monitoring is part of standard care it should be provided irrespective of research participation (Right 4(1) of the Code).

If the goal is to improve the monitoring of patients or the level of interaction with patients or families,²⁶ there are more straightforward ways to achieve it than patients being enrolled in research studies. The issues with a “best interests” test being applied to research with adults unable to consent can be summarised as follows:

- 1 “Best interests” requires researchers to meet a test that is almost impossible in a research context, namely that it is known at the time of enrolment that an individual will be personally better off by participating in the research than not, and that this outweighs the potential risks and burdens.
- 2 It results in some potentially valuable, but low risk research being prohibited, for example, comparisons of two standard treatments do not meet the best interests test because participants are no better off from being in the research.
- 3 It is possible that in the effort to demonstrate individual benefit, there is insufficient focus overall on assessing the **risk** to participants, which is also required as part of weighing up risks and benefits. This seems to be the implication from the submissions received, many of which argued that a test more explicitly focused on risk was needed.
- 4 “Best interests” requires demonstrating only net benefit to a person. It does not, however, incorporate any kind of risk threshold. In theory, if a case could be made for very high potential benefits, then the level of risk and burden permissible could also be high. This may not provide sufficient protection for adults who are unable to consent.

In summary, if we consider that some research involving adults unable to consent is appropriate, then the “best interests” test needs to be changed. There would also potentially be some other advantages in changing the test, such as creating a much clearer focus on risk in decision-making.

25 Manning, J. (2016), “Non-consensual clinical research in New Zealand: Law reform urgently needed”. *Journal of Law and Medicine*, 23: 516 at p.521.

26 It should be noted that there is no legal basis on which to argue for benefits to families — the Code is about individuals, so benefits to families should not be accepted as part of a benefits assessment.

The challenge is to construct a test that appropriately takes account of risks, burdens, and benefits for research participants.

What would be a better test? Options for a test to replace best interests

There are different approaches to defining risks and benefits. The definition and assessment of risk is a critical issue, given that “one of the fundamental ethical concerns about biomedical research is that it frequently exposes participants to risks for the benefits of others”.²⁷ This makes it important to have safeguards to protect the rights and interests of study participants, hence the inclusion in all research regulations and guidelines of some kind of test to do this. Nevertheless, Rid notes that “the ethics of risk is a relatively new area of enquiry and a general theory of acceptable risk still remains to be developed”.²⁸

Legislation and guidelines in different countries have taken different approaches. Examples include: best interests, no worse off, minimal/negligible risk, minor increase over minimal risk, risks over benefits to individual, and risks over benefits to society.

One important point to note is that “risk” always refers to the marginal increase in risk from participation in the research itself, not the overall risk associated with any interventions being given or the person’s condition.²⁹

Some of the key issues in considering options are:

- Whether the test should focus only on risk (and burden) to the participants, or whether benefits to the individual should also be incorporated into the test;
- How benefits to others should be taken into account; and

- Whether the risk test should be an absolute one or proportionate, that is, there is either an absolute risk threshold that cannot be exceeded, or risks and potential benefits are weighed in some way.

The most common suggestion from submitters for an alternative test was one based more explicitly on the risk of harm to the participant (and also the burden of participation). The suggestions included no risk or minimal risk, that the person would not be any worse off, or that any harm would not be permanent or invasive.

A number of submitters suggested that observational or non-invasive research or studies comparing two standard treatments would be acceptable and would meet the threshold of no or minimal risk. Some submitters commented that randomised controlled trials (RCTs) seemed “intuitively wrong”, but noted that there is already considerable variation in standard treatments based on clinician preference. Some said that RCTs would be acceptable as long as both groups received at least a standard treatment (e.g., no placebo group). Even this is not uncontroversial, with others arguing that clinician preference is not the only factor affecting choice between two standard treatments, and that sometimes the decision is based on patient factors. Thus, randomisation to standard treatments may not be consumer centred.

One of the most contentious issues is whether and how potential benefits, either to the individual or to others, should be considered alongside risk and burden. Submitters were divided on this, with some saying that the potential for an individual to benefit should be taken into account, while others felt that this would be ideal but not always possible, so should not be a rigid requirement. The idea that people unable to consent could be enrolled in research that might benefit only others drew

27 Rid, A. (2014), “Setting risk thresholds in biomedical research: lessons from the debate about minimal risk”. *Monash Bioethics Review*, 32: 63–65. Doi 10.1007/s40592-014-0007-6, p63.

28 Rid, *ibid*, p75.

29 See, for example, Berg, R.M.G., Moller, K. and Rossel, P.J.H. (2013), “An ethical analysis of proxy and waiver of consent in critical care research”. *Acta Anaesthesiologica Scandinavica*, 57: 408–416. Doi:10.1111/aas.12083.

strong reactions from some submitters, and they equated this with exploitation and using vulnerable people as “guinea pigs”. For some people, this is unethical and unacceptable.

However, the reality of research is that its primary purpose is to benefit others in the future, rather than the individual participants, although they may benefit from participation and/or from improvements in services resulting from the knowledge gained from the research. In reviewing the examples from other jurisdictions, the guidelines generally involve some kind of requirement for “individual benefit”. One person consulted suggested that not referring to individual benefit signalled “too strongly” that research was utilitarian, while others thought it was better to be honest and upfront about where the benefits accrue.

The review considered a number of possible options, including:

1. Status quo — best interests or net benefit
2. No risk
3. No more than minimal risk
4. Potential for individual benefit and no more than minimal risk (both tests are absolute)
5. Various conditional and proportionate options weighing up risk and individual benefit
6. Allow minor increase over minimal risk if compelling social value
7. Not known to be contrary to best interests

All options have pros and cons (as set out in Appendix 2) and were carefully considered. On balance, the preferred option is an absolute threshold of no more than minimal foreseeable risk and no more than minimal foreseeable burden, which is not exceeded regardless of any potential individual or societal benefit (Option 3).

This provides the greatest level of protection for consumers by setting a threshold that cannot be exceeded regardless of potential or presumed benefits. We considered also using the word “negligible” rather than “minimal”, but felt that this was tantamount to requiring no additional

risk at all, which would most likely preclude some observational studies and those involving the comparison of two standard treatments where, for example, additional blood draws might pose some marginal risk.

It is not proposed to incorporate a requirement for likely or potential benefit to the individual into the decision-making criteria. This has been one of the most difficult issues when considering principles for research with adults who are unable to consent:

Perhaps the most difficult and finely balanced issue ... is whether such studies should be able to proceed when there is no possibility of direct benefit or net overall benefit to the incapacitated person. If the judgment is that using people who cannot consent for themselves in experimental research in which there is no possibility of benefit to them and the only possible benefit is to future patients and to society is an affront to their intrinsic dignity and is ethically unacceptable, it is of no relevance that the research entails only minimal risk or none at all.³⁰

Whilst there may sometimes be benefit to individuals from participation in research (immediately or as future patients), continuing to require that there be potential individual benefit would do little to advance us from the current situation. It would also continue to exclude research involving comparison of two standard treatments, which submitters and experts almost universally agreed should be permitted. Advice from our experts is that it is better to be transparent about the purpose of research, which is about building knowledge to improve services for consumers in the future.

Some researchers said that, as part of the informed consent process, they often go to great lengths to ensure that potential participants who are deciding whether to consent to participation are not under the misapprehension that there is a guarantee that they will benefit from participating in the research. Yet when participants are unable to consent, researchers are required to demonstrate to ethics committees that there would be individual benefits for the participants.

30 Manning, *ibid* p530.

We considered whether a greater level of risk to individuals (even a minor increase above minimal risk) should be permitted if the social value of the study is compelling.³¹ We concluded that such studies should not be approved at all unless they have scientific and social value, and a higher social value should not be a justification for exposing research participants who are unable to consent to a greater than minimal level of risk (see later section on safeguards and other provisions).

A test that is explicitly focused on risks and burdens for participants would potentially provide better protections for vulnerable consumers than does the current “best interests” test, whilst also being more permissive of low risk but valuable research.

This proposed direction of travel is supported by the experts to whom we have spoken; however, the Health and Disability Commissioner Act requires consultation on any proposed changes to the Code. Two areas of practical considerations are discussed in the following section.

Practical considerations

Defining and assessing risk

Defining and assessing risk is notoriously difficult. “Risk” encompasses both the probability of harm occurring and the severity or magnitude if it does occur — so, the probability may be small but the consequences very serious; or there may be a higher likelihood of something occurring but with only minimal impacts. Even defining “small” is problematic in this context (is a one-in-one-hundred or a one-in-one-thousand chance of something occurring “small”?). The concept of minimal risk can also incorporate the potential for burden and inconvenience from participating in the research.

As noted above, Rid suggests that the ethics of risk is a relatively new area. She notes that different regimes provide different levels of guidance to decision-makers about how to define and assess risk. Some simply state “no more than minimal or negligible risk” and leave it to those charged with implementation to interpret what

this means. Others provide some interpretation such as “risks are minimal when they involve no likelihood of serious harm, permanent injury or death”, while others define risk of research in comparison to the risks of other activities, for example “risks are minimal when the probability and magnitude of harm or discomfort anticipated in the research is not greater than those ordinarily encountered in daily life”.³² Further work will be needed to develop suitable guidance about how to interpret and assess risk.

At the level of study approval, the ethics review and approval system would assess at a population level the foreseeable risk involved in research with adults unable to consent. A robust system is needed to ensure that risks in this type of research are being independently and objectively assessed to provide a very high level of protection for a vulnerable group of people. Experts spoken to considered that this ideally requires specialist expertise that may not always be available to an ethics committee. However, risks must also be assessed in relation to individual participants, not just the overall study. This is discussed below.

Population vs. individual risk assessments

An important question is how risk assessment should be considered in relation to the two stages of decision-making, that is, the approval of the overall study by an ethics committee, and the enrolment of an individual in an approved study.

An ethics committee should make an overall determination of the foreseeable risks and burdens of a particular study and require inclusion and exclusion criteria which, amongst other things, will determine the types of people who are eligible or ineligible to participate. This assessment is at a population level and covers risks and burdens in a general sense to the group of potential participants. However, when deciding whether to enroll an **individual** in a study, some assessment of the foreseeable risk and burden for that person is also required. This is not the role of an ethics committee.

31 See, for example, CIOMS guidelines.

32 See Rid for further discussion.

This raises several questions:

- Should an individual risk assessment always be carried out to take into account the particular characteristics of the individual? Or should the overall assessment and inclusion/exclusion criteria be sufficient to make the judgement that the research will have minimal foreseeable risk for **any** potential participant?
- If an individual assessment cannot be carried out (e.g., in emergency research where there is very little time available), should the person be able to be enrolled in the study or not?
- What should the nature of a risk and burden assessment for an individual be, and who would do it (note that this is discussed further in the next section on “Who decides?”)?

It should be remembered that the Code sets out the criteria for decision-making in relation to individuals, including the current “best interests” test, and risk for the individual must be assessed as part of this. Decision-making, including assessment of risks and burdens, cannot stop at study approval stage, but must apply to individuals as well.

As such, relying solely on inclusion/exclusion criteria is not generally sufficient to ensure that an individual’s circumstances have been adequately taken into account. Assessing risk and burden for an individual should form part of the decision-making process alongside other considerations such as any known wishes or objections (see section below), and is an important safeguard.

However, this is an example where the variety of circumstances and types of research mean that it may not be possible to construct a “one size fits all” approach, and that there may need to be exceptions in some cases, for example when it is not practicable to carry out an individual assessment in certain types of emergency research. Options for whether there should always be an individual risk assessment include:

1. Yes, and enrolment should not proceed without it.
2. No, just rely on inclusion/exclusion criteria.

3. Ideally yes but allow exceptions in certain circumstances when it is not possible to do a risk assessment and have additional safeguards (see Appendix 3).

Again, there is no ideal answer to this problem. The preferred option is to allow participants to be enrolled in a research study without an individual risk assessment only in limited circumstances. There should also be follow-up and monitoring of studies where this occurs (Option 3). This is discussed more fully in the section below on ethics review and approval.

Summary

The issues discussed in this section have been amongst the most complex and difficult in the review. There are no easy answers, and many different interests, perspectives, and values to be weighed up. The underlying question is about the appropriate balance in the regime that underpins carrying out health and disability research with adults who are unable to consent. Overall, the review has concluded that this balance should be shifted slightly to allow some research not currently permitted, primarily because without doing so, cohorts of consumers may be disadvantaged in terms of benefiting from evidence-based improvements in the understanding of their conditions and quality of care. However, a higher level of protection is needed for these participants than for people who can consent, and this must be explicit in our regime.

This will require developing a new test to replace “best interests” in the Code with regard to research involving participants who are unable to consent (but not services or treatment) with a preferred option of the introduction of a no more than minimal foreseeable risk and no more than minimal foreseeable burden test. This option excludes a requirement that individual benefit be demonstrated.

This section has focused only on the “best interests” test in the Code, and how risks, burdens, and individual benefits should be dealt with in decision-making about research involving adults unable to consent. The following section discusses what

the other principles and safeguards should be. HDC will not be recommending any change to the “best interests” test unless we are confident that the other safeguards set out in this report will be introduced.

Other provisions and safeguards relating to research involving adults unable to consent (Question 2)

Overview

If some research with adults unable to consent that is currently not permitted were to be allowed, and the “best interests” test were to be amended, such research should still be allowed only in limited circumstances. The critical question is what other provisions and safeguards need to be in place to support such a change in order to minimise the chances of unethical or harmful research occurring. Many submitters and others spoken to during the review stressed that research with adults unable to consent should be permitted **only** if there are adequate safeguards in place. As noted earlier in this report, we received comments about what those safeguards should include, as well as concerns that some existing safeguards need to be strengthened.

Three key sets of provisions and safeguards are needed:

- A comprehensive set of principles to underpin health and disability research involving adults unable to consent. These principles should cover decisions about both the approval of a research study, and the enrolment of an individual in an approved study. Whether they are set out in the Code or elsewhere, they should work together as a coherent set of principles.

- 2 The creation of a specialist ethics committee for this type of research. Ethics review and approval is the key procedural safeguard for protecting consumers.
- 3 Any changes to the Code and/or other aspects of the regime for health and disability research involving adults unable to consent should be monitored and evaluated with a particular focus on outcomes for consumers, with an initial report back in two years from implementation.

The principles are discussed first. These apply to decisions about study approval and/or enrolment of an individual in a study once it has been approved. The proposed test for assessing risk and burden discussed in the previous section would operate at both levels and, while ethics committees do not make decisions about enrolling individual participants, part of their role is to ensure that the researcher has robust protocols in place in relation to enrolling individuals, including how the researcher will give effect to the legal and ethical requirements.

A comprehensive set of principles

Study approval: Mandatory ethics committee approval

Issues

There is no general legal requirement in New Zealand for ethics committee approval to do health and disability research, including research involving adults unable to consent. Currently our system largely relies on indirect levers to ensure that studies have appropriate ethics approval, such as research being unlikely to receive funding or to be published without ethics committee approval, but there is no legal requirement except in some specific cases.³³

33 There are some specific requirements, for example, in relation to reproductive technology research under the Human Assisted Reproductive Technology Act 2004. Right 7(10) of the Code also requires ethics committee approval in relation to research with any body part or bodily substance removed or obtained in the course of a healthcare procedure if the person has not given informed consent.

The overwhelming majority of submitters felt that ethics review and approval should be required for this type of research, with several expressing surprise that this was not already the case. Only a few said that this requirement should not be mandatory, but this was largely because they felt that such research should never be allowed to be undertaken.

There was some confusion between the decision about study approval and the decision about enrolling an individual, with some apparently believing that ethics committees have a role in decisions about the enrolment of particular individuals.

Mandatory ethics committee approval was considered to be a minimum requirement for this type of research. This was felt necessary to ensure protection of vulnerable participants, provide openness and transparency, and to provide an objective and independent view of the ethics of the research. One person noted that ethics approval is already mandatory for animal research,³⁴ and felt that it is anomalous that it is not also the case for human research with vulnerable groups.

Some felt that inclusion in legislation is necessary to ensure that the requirement has “teeth”, but there were also nuances in the responses about how this should be put into practice. Several submitters noted that the consultation document mentioned only “ethics committee approval” but did not specify *which* committee, for example HDECs or IECs, and questioned whether this level of detail is needed in legislation.

A number of submitters and experts commented on what they saw as inconsistencies in the current requirements relating to HDECs, for example, that PhD research must be considered by an HDEC, but Masters level research and below needs to go only to IECs. The HDEC Chairs noted in their submission that it is not clear that all health and disability research is currently being reviewed by an ethics committee. These gaps and inconsistencies in pathways and rules were felt to be a weakness in the current system.

The Commissioner’s view is that ethics committee approval for research with adults unable to consent should be mandatory for research covered by the Code. Ethics committee approval should be a key safeguard in the overall system for carrying out health and disability research involving adults who are unable to consent. Relying on indirect levers such as requiring ethics committee approval for access to funding or the ability to publish is not a sufficient safeguard, and this needs to be strengthened.

Options

The review considered three options: status quo; make a recommendation to include the requirement for ethics committee approval in the Code; or recommend that this be considered as part of any wider system review (Table 2).

Inclusion in the Code would be a similar provision to Right 7(10)(b), which relates to the use of body parts and bodily substances, and says:

No body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved or used otherwise than ... for the purposes of research that has received the approval of an ethics committee.

“Ethics committee” is defined as:

- a. Established by, or appointed under, an enactment; or
- b. Approved by the Director-General of Health

34 Animal Welfare Act 1999, s83.

Table 2: Options for mandatory ethics committee approval

Options	Description	Pros	Cons
Status quo	No legislative requirement for ethics committee approval for health and disability research with adults unable to consent	<ul style="list-style-type: none"> • Low cost 	<ul style="list-style-type: none"> • Weak protection for consumers • Relies on indirect levers to ensure ethics committee approval. Possible not all research is receiving ethics committee approval
Include ethics approval in Code	Amend the Code to include a provision to require ethics committee approval for research with adults unable to consent (similar to Right 7(10)(b))	<ul style="list-style-type: none"> • Provides protection for all consumers covered by the Code • Consistent with other Code rights 	<ul style="list-style-type: none"> • Would still leave a gap for research not covered by the Code so may also need to be included in other legislation to be inclusive
Do nothing now and consider as part of wider system review	Leave it to a wider system review to consider best legislative vehicle for mandatory ethics approval	<ul style="list-style-type: none"> • Could provide coverage for all consumers unable to consent who are involved in research, not just those covered by the Code 	<ul style="list-style-type: none"> • Wider review may not result in new or amended legislation

The preferred option, at least in the short term, is to include the requirement for ethics approval for this type of research in the Code itself, similar to Right 7(10), and with the definition of “ethics committee” as currently in the Code. This would still leave a gap for health and disability research not covered by the Code. However, the Commissioner does not intend to recommend that the Code’s jurisdiction be extended.

Study approval: Alternative participants and alternative research designs

Issues

One of the arguments for allowing some research that is currently not permitted to be carried out with adults unable to consent, is that sometimes this is the only way to build the knowledge to better understand their conditions and/or to improve treatment and services. Thus, guidelines for research involving adults who are unable to consent typically require that the research should involve only this group of participants if it is not possible to carry it out with people who are able to consent (sometimes referred to as the “necessity condition”³⁵). Examples from existing guidelines and legislation are shown in Table 3.

35 Manning, *ibid*, p516–530.

Table 3: Examples of wording for the principle that the research cannot be done with alternative participants

Source	Example
NEAC guidelines	Studies should not be performed with vulnerable groups if they can be performed adequately with other groups
Declaration of Helsinki	The research cannot instead be performed with persons capable of providing informed consent
Council for International Organizations of Medical Sciences (CIOMS)	The interventions and procedures should be studied first in persons who can give consent when these interventions and procedures target conditions that affect persons who are not capable of giving informed consent as well as those who are capable, unless the necessary data cannot be obtained without participation of persons who are incapable of giving informed consent
Mental Capacity Act (England and Wales)	There must be reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the project has to be confined to, or relate only to, persons who have the capacity to consent to taking part in it
Adults with Incapacity Act (Scotland)	No research shall be carried out on any adult who is incapable in relation to a decision about participation in the research unless research of a similar nature cannot be carried out on an adult who is capable in relation to such a decision.

The consultation document asked whether 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. There was a strong recognition that it is not always possible to generalise findings from research with populations able to consent (who either do not have the relevant conditions or who have the condition but not to the extent that it means they are incapable of consenting) to populations unable to consent, and that research with these groups is therefore sometimes necessary. Submitters were in broad agreement with the principle that it must be demonstrated that the research could not be done in any other way.

Some people, however, commented that such a provision could become overly restrictive if not framed well. Some felt there was a risk of making it difficult to do research that would benefit people with particular conditions, again leaving them as “therapeutic orphans”:

The purpose of such a requirement should be to prevent the exploitation of vulnerable people, but it must also ensure that the opportunity for a particular group to participate in research is not closed off.

Options

This principle is an important safeguard for consumers who are unable to consent, and should be a fundamental condition of study approval. It is a key criterion that should be met before such research studies are approved by ethics committees. This principle should be extended to clarifying that research with adults unable to consent should be done only if there is no other suitable methodology to answer the research question.

This principle relates to study approval rather than individual enrolment. Currently, it is one of the provisions in the NEAC guidelines, rather than in the Code. We anticipate that this provision will continue to be included in the NEAC guidelines following the current review.

Study approval: Relevance to the condition or group (benefits to others)

Issues

Another principle commonly used in guidelines about such research relates to the benefit the research would have to wider society. This is usually framed so that it is a requirement that the research should be relevant to the participants’ condition or group in some way, rather than society in general. Focusing on the participants’ condition or group is a way to prevent these groups from being convenient research subjects.

Examples of wording from different regimes are shown in Table 4.

The consultation document asked whether research on an incompetent person should be permitted if the research may or may not benefit the individual participant but may benefit other people. This question elicited strong comments from some submitters who had concerns about utilitarianism and argued that research should not be about benefiting people in the future:

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.

However, as stated above, health and disability research is primarily aimed at generating knowledge to benefit other people rather than individual research participants. The difficult ethical question is whether research should be permitted if it is focused on improving services for people who do not have the impairing condition experienced by the participants.

Table 4: Examples of wording for the principle that research must be relevant to the person’s group

Source	Example
NEAC guidelines	The study should ask questions that matter to the participant’s community and the answers should benefit the community
Declaration of Helsinki	The study is intended to promote the health of the group represented by the potential subject
CIOMS	Not mentioned
Mental Capacity Act (England and Wales)	The research must be related to the impairing condition that causes the lack of capacity, or to the treatment of those with that condition. “Impairing condition” means a condition which is (or may be) attributable to or which causes or contributes to (or may cause or contribute to) the impairment of, or disturbance in the functioning of, the mind or brain
Adults with Incapacity Act (Scotland)	[Not unless] the purpose of the research is to obtain knowledge of <ul style="list-style-type: none"> i. The causes, diagnosis, treatment or care of the adult’s incapacity ii. The effect of any treatment or care given during his incapacity to the adult which relates to that incapacity

It is an important principle that the benefits of the research should not just be generalised to wider society, but relate specifically to the participants as much as possible.

Options

One of the key safeguards in place should be a very clear requirement for study approval that research with adults unable to consent should be carried out only when it is directly relevant to the wider group to which the research participants belong.

There are a number of ways to frame this provision, as shown above. The current NEAC guidelines for intervention research on non-consensual studies do not mention this issue explicitly, but the section on research with vulnerable people says that “the study should ask questions that matter to the participant’s community, and the answers should benefit the community”.³⁶ In regard to principles for health and disability research with adults unable to consent, this should be made more explicit. “Participant’s community” is open to interpretation, as everyone belongs to multiple communities.

Study approval: Scientific merit and social value

In relation to the general question about the benefits of research, a number of submitters also mentioned the issues of scientific merit and social value (although there was no specific question on these issues). To be useful, research must be robust (for example, design and methodology), worthwhile (provide social value), and answer a genuine research question. Furthermore, as NEAC noted in its submission, knowledge can be advanced through both positive and negative outcome research, that is, both what works and what does not work.³⁷

During the review, many commented that research that does not meet these standards is unethical, and in fact these principles should underpin all research.

These should be specific principles, and go beyond ensuring only that research with adults unable to consent is relevant to their group or condition. Such people should also not be involved in research unless it has scientific merit and social value.

Individual enrolment: Taking the person’s views into account, including dissent

Issues

Typically, decision-making regarding the enrolment an adult who is unable to consent as a research participant includes consideration of that person’s views or known wishes. Berger notes, for example, that decisions for adults unable to consent often “follow a hierarchy of three standards crafted to maximally respect individual autonomy . . . known wishes, substituted judgments and best interests”.³⁸ “Known wishes” refers to a person’s prior direct expression of preference, while “substituted judgments” requires decision-makers to make decisions that reflect a potential participant’s views and values.

There can be particular challenges with identifying either a person’s specific wishes or his or her views and values in relation to research, and using that to inform a decision about the person’s participation without consent. Many people have rarely thought in advance about participating in research in even a general way. Berger suggests that research decisions are typically more complex than decisions about treatment.³⁹

36 National Ethics Advisory Committee (Wellington, Ministry of Health, 2012), *Ethical Guidelines for Intervention Studies: Revised edition*, p15.

37 Likewise, the CIOMS guidelines state that “negative and inconclusive as well as positive results of all studies should be published or otherwise made publicly available” (p91).

38 Berger, *ibid*, p45.

39 Berger, *ibid*, p45.

The decision-making standards required in research can also be problematic. Even if someone has expressed a general view about research or holds values that are supportive of research in general, determining from this what the person would want to do in a specific situation is speculative.

The consultation document did not include a specific question about this issue, but throughout the review there has been a theme of how to give regard to a person's wishes if he or she is unable to give informed consent. This included discussions of will and preference, advance directives, and expressions of dissent. Many people commented on the shift in the area of disability issues from a paradigm based on substituted decision-making, to one based on supported decision-making.⁴⁰

The concept of supported decision-making is important because it suggests that with the right kind of support, people may be able to express their will and preference. Some submissions emphasised that people may be able to make decisions about some aspects of their lives, but not all, and that there are risks in assuming that inability to consent or decide about some things is generalisable to all matters.

The definition and assessment of capacity to consent is an important and complex issue, but one that is outside the scope of this review. The Code already covers these issues, including, in Right 7(3):

Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.

The Code also requires decision-makers to take into account the wishes (both specific and general) of a person who is unable to consent, as far as possible. Right 7(4), for example, says:

[T]he provider may provide services where ... reasonable steps have been taken to ascertain the views of the consumer; and ... if the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent ...

In addition, Right 7(5) says that “[e]very consumer may use an advance directive in accordance with the common law”.

This review relates to people who completely lack the capacity to give informed consent to participate in research. Giving informed consent requires the ability to understand information about the objectives of the research and the risks, burdens, and benefits involved, and to make a choice about those — this is different from assent, or will and preference.

Submitters' views differed about what should happen if the person's wishes are unknown. Some people felt strongly that if it could not be demonstrated that the person would want to be in the research, then that person should be excluded:

Disabled people with impaired decision-making should be given maximum protection from becoming the subject of non-consensual research if their will and preferences about research participation are unknown.

Others argued for a presumption of altruism, saying that most people would want to “help others” if they could.

40 United Nations Convention on the Rights of Persons with Disabilities.

Advance directives were raised by submitters several times throughout the consultation. Consumers have the right under the Code to make their wishes known via an advance directive (Right 7(5)). In reality, advance directives are likely to be of more use in some circumstances than others. In general, an advance directive is more relevant if the person is aware that he or she may in the future be unable to consent to participate in research, and wants to make a decision in advance. For example, an advance directive may be of use where someone has a progressive illness with a reasonably known trajectory. In emergency research situations it is unlikely that the person will have considered the matter or made his or her wishes known.

The HDEC Chairs considered that the decision to take part in research must be made on a case-by-case basis, following the provision of full information about the particular risks of a study. They considered that even the use of advance directives was therefore problematic because, at best, the participant would be likely to express a blanket provision about participation in research, which was not specific enough to amount to advance consent to particular research.

However, if a person made an advance directive that he or she did not wish to be enrolled in any research, then that person should not be enrolled.

Overall, the rights in the Code provide for taking a person's wishes into account, whether it be having regard to the person's general views and values, or specific and known wishes, or the right to supported decision-making when there is some capacity to consent. However, for the reasons discussed above, these rights can be difficult to put into practice in a meaningful way.

Dissent

A particular issue is how to take into account indications of dissent to participating or continuing in research, for example facial expressions indicating pain or fear. It was commented that a person may indicate an unwillingness to participate, and that this should be respected, for example by approaching the person again later.

Other legal and ethical frameworks mention this explicitly. The CIOMS guidelines, for example, state that any explicit objection by the person must be respected even if an AR has agreed to participation.⁴¹ The Mental Capacity Act includes requirements that a person must be withdrawn from a study without delay "if he indicates in any way" that he wishes to be withdrawn (s33(4)).

The consultation document included a question about taking into account expressions of dissent. Most people said that such expressions should be respected, and that this should be in law, although a large proportion were unsure or said no, and a number of people did not respond to this question.

Some people felt strongly that any indication of dissent should be respected, and that people should not be enrolled or should be withdrawn immediately. Others, however, thought that it was more complicated, and said that facial expressions or other indications of apparent dissent could be difficult to interpret, or that expressions of fear or pain could be due to factors other than the research. Some felt that as a general principle, dissent should be respected, but that dissent could be context dependent, raising difficulties about how much this principle should be codified in law. For example, an expression of discomfort could indicate that a person is upset about an intervention that would be happening anyway, rather than the research. This suggests that some flexibility is needed in how this general principle is put into practice.

41 "International Ethical Guidelines for Health-related Research Involving Humans" CIOMS 2016 Guideline 16, p62.

Researchers who are experienced in doing research with people with intellectual disabilities have commented on the “fine line” they sometimes tread when a person indicates that he or she does not wish to participate or to carry on:

We honor their initial expressions of refusal but then later try again to carry out the testing. To what extent should we encourage individuals who have limited means for expressing themselves to continue with a research procedure? ... [I]t is not always easy to distinguish when a participant is experiencing transitory distress or discomfort and when that participant is actively unwilling to be involved in our research.⁴²

The concern in this issue is to strike an appropriate balance between respecting an individual’s apparent wishes when they may not be clear, and in not excluding people from research to the extent that it becomes unviable to do research of relevance to their wider group.

Options

Expressions of dissent should be respected, but the question is how absolute the requirements should be — should there be a blanket rule that any expression of dissent should mean that the person should not be enrolled or continue to participate in research, or a more general principle that expressions of dissent should be respected and responded to on a case-by-case basis, with appropriate guidance developed (Table 5)?

Experts spoken to considered that some flexibility is needed in how best to respond to expressions of dissent. We acknowledge that researchers are generally concerned about the welfare of vulnerable participants and respond appropriately to their cues. The preferred option is therefore that there should be a specific provision about respecting expressions of dissent, but that this should be responded to on a case-by-case basis. Guidance on this could be developed as part of the NEAC guidelines.

Table 5: How should expressions of dissent be responded to?

Options	Description	Pros	Cons
Person should not participate in research if any dissent is expressed	Any expressions of dissent should mean the person should not be enrolled in research (or should be withdrawn)	<ul style="list-style-type: none"> • High level of protection for participant 	<ul style="list-style-type: none"> • Does not allow any flexibility to take into account different circumstances • Could make it difficult to recruit and retain enough participants in certain types of research
Dissent should be respected but flexibility in how to respond	Expressions of dissent should be respected but this should be dealt with on an individual basis	<ul style="list-style-type: none"> • Allows some flexibility • Makes research more viable 	<ul style="list-style-type: none"> • Relies on researcher skill and judgement to decide whether to proceed

42 Tager-Flusberg, H., Skwerer, D., Joseph, R., et al (2017), “Conducting research with minimally verbal participants with autism spectrum disorder”. *Autism*, 21(7): 860.

Individual enrolment: Who decides to enrol an individual who cannot consent into a research study?

Issues

When individuals cannot consent for themselves, their wishes, if known, should be determinative. If not, someone else must decide whether they will be enrolled in a research study. Currently, the decision to enrol an individual who cannot consent in health and disability research must be made either by the Court (if a personal order has been made) or by someone entitled to consent on behalf of the consumer (such as an AR, subject to the limitations in s 18 of the PPPR Act). In the absence of such a person, for research covered by the Code, the decision is currently made by “the provider” according to the criteria set out in Right 7(4).

The Act provides definitions of “disability services provider” (“any person who provides or holds himself or herself or itself out as providing, disability services”) and “health care provider” (which includes any health practitioner and any person “who provides or holds himself or herself or itself out as providing, health services to the public”). There may be multiple providers involved in providing services to any consumer. In addition, the researcher and provider(s) may be different persons, in order to minimise the risk of conflict of interests.

The provider must ascertain the views of the consumer to determine whether participation in the research would be consistent with the person’s wishes. If the provider has not been able to ascertain the views of the consumer, there is a requirement in the Code 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. If there is no one available and the consumer’s views are not known, the decision rests solely with the provider to determine whether enrolment is in the person’s “best interests”.

The consultation document asked whether there should be any changes to who can decide to enrol a person unable to consent in research, including changes to the roles played by the various possible decision-makers. Options for those who might play a role in decision-making were EPOA⁴³/welfare guardian, family/whānau, a provider not involved in the research (e.g., a person’s responsible clinician or GP), the researcher, or someone else.

This was one of the most challenging questions, and many submitters did not answer it or answered only partially.

Amongst those who answered, there was little agreement and few clear themes. Most commonly, people felt that ARs should be able to consent/decline or should at least be consulted. The next most common choice was for family/whānau to be involved, but often this was in a role of being consulted rather than deciding. Some said that family were in the best position to make the decision, but others said that family could not always be trusted to do the best thing for the person. Many people were concerned about the researcher also being the decision-maker, owing to the potential for conflict of interests, but others thought that this in fact would mean that the researcher was in the best position to make an informed decision. One suggestion was for an independent advocate to be involved in the decision-making.

As in many of the other questions, many people said that it depended on the situation and was to some extent a question of what is practical. Substituted decision-making is one of the most complex and challenging issues in the area of ethics relating to incapacity, so it is not surprising that there was such a lack of clear options. In addition to the issue of how to take the person’s own wishes into account (as discussed in the previous section), the following issues emerged:

43 An EPOA cannot make a decision about a “significant” matter relating to the person’s care or welfare unless the EPOA has been activated (invoked) by way of medical certification.

1. *The practicalities and appropriateness of ARs deciding*

It is relatively rare for there to be an activated EPOA or a welfare guardian appointed by the Court available in emergency research situations, and even where there is such an AR, the person's ability to decide about participation in health and disability research is currently limited. The ability for ARs to make these decisions is determined by the PPPR Act, which specifically prohibits ARs being able to enrol someone in a "medical experiment" other than one to be conducted for the purpose of saving that person's life or of preventing serious damage to that person's health. However, it would seem that disability research involving interviews or the observation and comparison of care options would not be medical experiments, and so an AR could consent to the person's participation.

In order for ARs to be able to consent to the person's participation in any medical experiment, amendments to the PPPR Act would be required. There is some argument that decisions an AR might make about treatment or services that are in the person's "best interests" are very different from decisions about participation in research, and that ARs are not necessarily well placed to make decisions about research. More fundamentally, one international expert consulted commented that while all statements about decision-making in this context default to the legally authorised representative, there is usually little if any discussion about what makes that person **ethically** able to decide on someone else's behalf.⁴⁴

This requires a more fundamental review of these provisions of the PPPR Act and the issue of substituted decision-making than is in scope for this review, and would need to be led by the Ministry of Justice. As such, this review assumes that the legal status quo remains regarding

ARs' ability to consent to research participation on behalf of someone else. However, if an AR were available at the time of the decision being made to enrol a person in research, the AR would be likely to be a "suitable person" to advise the provider, as per Right 7(4).

2. *Clarity of who the decision-maker is*

In the absence of anyone else entitled to consent on behalf of the consumer, the Code says that the "provider" will be the decision-maker. However, the definition of "provider" in the Health and Disability Commissioner Act is broad and, in relation to health and disability research, it is not always clear who the provider is, because of the range of types of research and circumstances in which the research is carried out. The researcher may not be the provider in the sense of providing health or disability services to the consumer, for example, a researcher may collect data about interventions provided in the course of the provision of services by someone else. There is a need to clarify who the decision-maker should be for the purposes of different types of research involving adults unable to consent, and the respective duties of the researcher and the provider.

3. *Conflict of interests*

The provider may also be the researcher or closely connected to the researcher, raising issues of possible conflict of interests or coercion. Conflict of interest is currently managed through ethics committee processes. For example, ethics committees may require the approach to potential participants to be made by a third party who is not providing services to the proposed participant, such as a research nurse. However, if the prospective participant is not able to consent, other processes are necessary to manage the potential for a conflict of interests. There should be specific requirements for ethics committees to

44 Personal communication with Professor Jeffrey Berger, 28 November 2017.

address this issue in cases where research participants are unable to consent, for example, by requiring that the decision-maker be independent from the research.

4. *Role of families*

A family member who is not an AR does not have the power to make decisions on behalf of a person aged 18 years or over who is unable to give informed consent. Many submitters said that they would want their family or others close to them to have a greater role in decision-making than currently. This is consistent with research that indicates that when asked, people often say they would like their family to make the decision for them.⁴⁵

Some researchers questioned how realistic family decision-making would be, especially in critical care situations, and raised the issue of whether families could really give informed substituted consent, especially if there is an assessment of risks and benefits to be made. Families may misunderstand the nature of critical care research and believe it involves special therapeutic treatment for their family member.⁴⁶ It was also suggested that asking families to make such a decision in a situation that may already be traumatic could be overly burdensome, although others thought that this was a paternalistic view, pointing out that families should not be denied a role in decision-making because it may be difficult for them.

5. *One size may not fit all*

In some types of research it would be impractical to consult other suitable persons or involve them in decision-making. This is especially so in emergency research where there is little time to consult others. This is a complex issue and is discussed separately below.

Options for who should decide on individual enrolment

Options for who decides on individual enrolment range from status quo to an entirely new regime with different decision-makers (Appendix 4). There may be several providers involved with a particular consumer, and currently the Code has no order of priority of decision-maker. The specialist ethics committee must determine the appropriate provider to make the decision. The preferred option is to retain the status quo at this time, but with some additional enhancements to provide further safeguards for these vulnerable participants.

These enhancements are designed to enable providers to continue to decide about individual enrolment, but to add in further protections for potential research participants, including managing conflict of interests, the weight given to the wishes of the person himself or herself, and a greater role for other suitable persons, such as ARs or family/whānau. Enhancements could include:

- Specific requirements that ethics committees must ensure adequate protocols to manage the situation where a provider (decision-maker) is also the researcher, to ensure that there is no conflict of interest or coercion;
- A continuation of the requirement to take the person's known wishes into account as far as possible, especially any prior objections to research. This might include greater use of advance directives to make wishes about research known where practicable (see previous section);
- Expressions of dissent by the participant should be respected (see previous section);
- A continuation of the requirement to consult with other available suitable persons, including ARs where applicable; and
- Introducing a power of veto so that the other suitable persons, including ARs, can veto participation in research. This should be able to be exercised on any grounds, i.e., not restricted to consideration of the potential participant's wishes, and by any one suitable person.

45 Berg, R.M.G., Moller, K. and Rossel, P.J.H. (2013), "An ethical analysis of proxy and waiver of consent in critical care research". *Acta Anaesthologica Scandinavica*, 57: 408–416. Doi:10.1111/aas.12083.

46 Berg et al, *ibid*.

What happens when it is not possible to consult with others prior to enrolment?

Consultation with others prior to enrolment may not always be practical. There are two key scenarios where this might be the case:

1. There is insufficient time to consult with others before enrolling a person in research, e.g., in some emergency research. This is likely to be known at the time of study approval, since it is a characteristic of the research itself that there will not be time to consult; and
2. The person does not have an AR or any other suitable person who could be consulted. This is unlikely to be known at the time of study approval, because it is not known in advance who amongst potential participants would not have people who could be consulted.

There are multiple options about whether enrolment should be permissible if no one else can be consulted (Appendix 5). A strict requirement to always consult others might make it impossible to do some types of emergency research, and there may be a rationale for providing an exception to the general rule so that potentially valuable research can proceed. Additional safeguards that could be introduced might be a requirement to consult with others as soon as possible after enrolment, and the possibility of the person consulted withdrawing the person or prohibiting use of the person's data. Another safeguard might be a requirement for stricter auditing and reporting in relation to research with adults unable to consent where no suitable person has been able to be consulted.

However, there are situations where a person does not have an AR or anyone interested in his or her welfare who could be consulted, for example a person with advanced dementia who has no AR, family, or other person interested in his or her welfare. This group is particularly vulnerable and should not be enrolled in research. The key difference between the emergency research situation and this scenario is that, in the emergency research situation, an absolute prohibition on enrolment without consultation with others would mean that whole research studies could not proceed. In the latter, there is

no reason the study cannot proceed, as there will undoubtedly be other suitable participants for whom it is possible to consult others (unless not having an AR, family, or friends is a variable in the research study).

This issue presents a challenge, as it is difficult to construct general rules that apply to all scenarios. In the emergency research scenario, the preferred option is to allow enrolment to proceed but to consult as soon as possible afterwards with available suitable persons, plus require auditing and reporting of research where this has occurred. However, in the scenario where it is a characteristic of the individual rather than the research study that precludes consultation, the preferred option is to allow the study to proceed but exclude individuals for whom there has been no consultation with suitable persons who are interested in the individual's welfare.

Individual enrolment: Consent upon regaining capacity

Issues

In some circumstances, an adult who is unable to consent may be enrolled in research and then subsequently regain capacity. The consultation document sought views on whether the law should be changed to allow delayed or retrospective consent to be sought from a person who has regained capacity to participate in research.

Amongst people who addressed this topic, the most common view was that the concept of delayed consent is an "oxymoron", and that "it is not possible to consent to something that has already happened". Others commented that the concept "makes a mockery of informed consent", is not a meaningful one, and could possibly be coercive if someone felt that they had to agree to something that had already been done. Many submitters, however, felt that if people regain the capacity to consent after they have already been enrolled in research, they should be provided with information about the research and, if practicable, have the opportunity to consent or refuse to consent to continued involvement in the research if it is ongoing, and also have the opportunity to decide whether any data about them that has already been collected can be used.

The concept of delayed or retrospective consent is illogical, as it does not make sense to seek consent for something that has already occurred. A more useful framing of this issue is, first, to consider the conditions under which someone may be enrolled in research without his or her consent, and, secondly, to have clear rules for what happens should the person regain capacity. This should be in respect of continued participation in the research and/or the use of data that has already been collected.

Where practicable, when someone regains the capacity to consent, he or she should be asked as soon possible whether or not he or she consents to continue in the research study and/or to the continued use of his or her data. A test of what is reasonable in the circumstances would need to be applied, for example, if someone regains capacity after a significant period of time, it may not be practicable or reasonable for the researcher to attempt to gain consent about either participation or use of data.

Summary of principles

The discussion above outlines the general principles that should underpin any regime for research with adults who are unable to consent. These are in addition to other rights already set out in the Code, such as rights to be treated with dignity and respect. They are written as principles, and further drafting of precise wording of any changes to the Code would be necessary.

Changing “best interests” to a no more than foreseeable minimal risk and no more than foreseeable minimal burden threshold would be a key change. The review does not propose changes to the core provisions for who decides about enrolling an individual in research when the individual is unable to consent. As a pragmatic solution, some additional safeguards are proposed, including the introduction of a right of veto by suitable persons. The management of conflict of interests where the researcher and provider are the same person or closely

aligned should be more transparent. Delayed consent is not a valid concept, and should not be introduced; however, participants who regain capacity to consent should be informed about the research and asked whether or not they consent to future participation (where practicable) and/or for the ongoing use of their data.

The review concludes that certain principles should be included in the Code, whereas others fall within the ambit of ethics committees. In relation to this, NEAC’s submission to this review also noted that:

Law and ethics are not the same thing, but they need to enable each other to function. Legislating ethical principles is problematic. Legislation should be permissive of good ethical practice, but should not define it.

Currently, principles relating to study approval are generally found in the NEAC guidelines, while principles relating to individual enrolment are found in Right 7(4) of the Code (noting that the “best interests” test is relevant to both). Those principles that are in the Code are effectively in law, and can be changed only by the Commissioner making a recommendation to the Minister for a Code amendment, and then following normal legislative processes for regulatory change.

Principles that appear in the NEAC guidelines have regulatory backing, through Right 4(2) of the Code, which states that “[e]very consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards”. For the purposes of Right 4(2), NEAC guidelines constitute ethical standards and therefore apply to any research that is covered by the Code.

See Table 1 for a summary of the proposed principles for health and disability research involving people unable to consent.

Ethics review and approval

Issues

Ethics review and approval is a critical aspect of the system relating to health and disability research. The national system of committees to provide ethical review and approval of health and disability research was developed in direct response to the inquiry into the “unfortunate experiment” at National Women’s Hospital,⁴⁷ with the primary purpose of focusing on outcomes for patients and their protection.⁴⁸ NEAC has an important role in providing independent advice on ethics matters, and in the development of national guidelines for health and disability research.⁴⁹ Along with the Health and Disability Commissioner and the Code, this system forms a key part of the safeguards for protecting and promoting consumer rights.

The HDC review did not set out to review the health and disability research ethics system, with the only directly relevant question in the consultation document being about whether ethics committee approval should be mandatory for research involving adults unable to consent. Throughout the review, however, we heard from submitters and other experts about the importance of the research ethics system, and that it would form a critical component of the additional safeguards needed should some research that is not currently allowed involving adults unable to consent be permitted. There was also a view that the ethics oversight needs to be more rigorous for research with adults unable to consent than with other types of research, given such consumers’ particular vulnerability.

The full range of views expressed by submitters is summarised in the “Summary of Submissions” document.

A critical issue is that generally there is no independent review of the risks and benefits of the proposed research, with researchers themselves providing this analysis. Risk assessment is a specialised area and is dependent on the type of services being researched. HDECs may not necessarily always have access to this level of specialist expertise (either on the committees or the resources to commission advice themselves).

Options

The current review of the NEAC guidelines and HDEC SOPs provides a vehicle for addressing some of the issues above and in previous sections of this report. Areas could include:

- Consolidate all ethics guidance relating to research involving adults unable to consent into one place (currently split between research with vulnerable people and non-consensual research)
- Update and amend guidance in line with the suggested principles:
 - Amend “relevance to community” (Principle 3 of the current NEAC guidelines)
 - Guidance on dissent (Principle 7 of the current NEAC guidelines)
 - Guidance on consent following regaining capacity to give consent (Principle 8 of the current NEAC guidelines)
- Assess at a population level whether the research will involve no more than minimal foreseeable risk and no more than minimal foreseeable burden (Principle 6 of the current NEAC guidelines)

47 *The Report of the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women’s Hospital and Into Other Related Matters* (1988): [http://www.moh.govt.nz/notebook/nbbooks.nsf/0/64D0EE19BA628E4FCC256E450001CC21/\\$file/The%20Cartwright%20Inquiry%201988.pdf](http://www.moh.govt.nz/notebook/nbbooks.nsf/0/64D0EE19BA628E4FCC256E450001CC21/$file/The%20Cartwright%20Inquiry%201988.pdf).

48 Peart, N. (2016), “Health and disability research ethics committees in New Zealand: Will the current system prevent another ‘unfortunate experiment’?”, in Henaghan, M. and Wall, J., *Law, ethics, and medicine: Essays in honour of Peter Skegg* (Thomson Reuters: Wellington), pp 211–242.

49 NEAC recently consulted on “Draft National Ethics Standards for Health and Disability Research” <https://neac.health.govt.nz/consultations>.

- Guidance on the management of alternative participants or research design (Principle 2 of the current NEAC guidelines)
- Guidance on the management of conflict of interests in research involving adults unable to consent when the researcher and provider are the same or closely aligned (Principle 6b of the current NEAC guidelines)
- Require research protocols to specify what will happen if individual risk assessment and consultation with suitable others is not possible (Principles 5a and 6d of the current NEAC guidelines).

The two main options to enhance the risk assessment process that were considered during this review were:

- 1 Establish an expert panel that would be available to develop guidance and give advice about risk assessment to any ethics committee considering research involving adults unable to consent; or
- 2 Establish a specialist ethics committee that would be responsible for reviewing all health and disability research involving adults unable to consent. Risk assessment expertise could be provided by members of the committee, and the committee itself should also have the ability to commission independent peer review. This would enable expertise in issues of research where adults are unable to consent to be developed and consolidated. A specialist ethics committee for research with adults unable to consent could also take on responsibility for auditing and follow-up of individual research studies, and play a broader oversight and monitoring role of such research.

These options would require resources, and cost-effective options would need to be considered. For example, the specialist committee might consider only research that would otherwise come to an HDEC, and Institutional Ethics Committees would be unaffected. One option might be to carry out audits of a subset of research, for example, emergency research where no risk assessment could be undertaken or no

suitable person was able to be consulted. Public reporting would aid transparency and support confidence and trust in the system.

Some submitters and experts consulted supported the idea of a specialist committee for research with adults unable to consent, while others thought it would be impracticable and resource-intensive and that it was better to have such expertise spread across all the HDECs. For those who supported a different approach to ethics review and approval for research with adults unable to consent, the main priority was to have specialist risk assessment, with or without a specialist ethics committee. This could be achieved through an expert panel established to advise HDECs, although a specialist committee that considered the entire research proposal would allow greater consistency and enable all ethical and other considerations to be considered together in an integrated way.

HDC's preferred option is for a specialist ethics committee to be established on the basis that adults unable to consent to participation in research are a highly vulnerable group and require a higher level of protection than research participants who are able to give informed consent.

Monitoring and evaluation

The final safeguard is that there should be monitoring and evaluation of any changes made to the rules relating to research involving adults unable to consent. A particular focus of any such monitoring and evaluation should be on the outcomes for consumers, and in particular whether the protections in place for consumers are robust enough once implemented. A specialist ethics committee could play a role in the monitoring of individual research studies, as described above, but there is also a need for a system-level evaluation to be undertaken.



Section 4:

Conclusions

Informed consent is at the heart of the Code of Health and Disability Services Consumers' Rights, and this review has raised multiple difficult challenges about whether we should allow some research not currently permitted under Right 7(4) involving participants who are unable to give informed consent.

My paramount concern is to do what is best for consumers. This involves both protecting individual consumers who are unable to consent, and enabling low risk ethical research that could help to improve treatment and services. There are difficult trade-offs, because research by its very nature requires some people to take risks and undergo burdens for the benefit of others. Finding the right balance to meet these different objectives, priorities, and values has been the central task of the review.

The “best interests” test in Right 7(4) works well for the provision of treatment and services, but it is not the right test for research, and acts as a barrier to potentially valuable low risk research. A more explicitly risk and burden based test, along with more robust and independent assessment of risk by a properly resourced specialist ethics committee, would protect vulnerable consumers whilst allowing such research to proceed.

The “no more than minimal foreseeable risk and no more than minimal foreseeable burden” test should be part of a comprehensive set of principles relating to health and disability research involving adults unable to consent. Additional safeguards can be introduced to ensure that a wider group of people are involved in the decision-making, including being able to veto the person's participation.

Amendments to the Code will be required to incorporate the recommended provisions. However, the exact format of those changes will need to be determined. I do not favour removing research from the Code, as protection of the

rights of participants in health and disability research was one of the key motivations behind the establishment of the Health and Disability Commissioner and the Code. Nor do I favour extending coverage of the Code to include all research.

Throughout this review, I have constantly asked myself and others, “What are the risks and benefits of making changes to allow some research with adults unable to consent that is currently not permitted?”, and, “Is it worth doing?” The actual impact of allowing some research that is currently prohibited is likely to be relatively small in terms of numbers of research studies. But for the consumers who stand to benefit from improved treatment and services, the impact could be significant, and thus the changes are worth making — provided the right safeguards are in place.

I have emphasised the need for additional safeguards as a pre-condition for recommending amendments to the Code. This is not to imply that ethics committees are doing a poor job, or that researchers are behaving unethically. The competence, integrity, and goodwill of individuals in the system to do the right thing are necessary but not sufficient. We need an additional layer of protection for adults who are unable to consent to participation in research, with appropriate checks and balances. The system also needs to be transparent, clear, and simple to navigate. It is important to make it easy for people to do the right thing.

The public must have trust and confidence in the system that governs research, and in those who undertake it. Trust and confidence depend on people being treated with dignity and respect and having their autonomy upheld, and on being protected from harm. This requires a transparent and robust system that is *perceived* as respectful, trustworthy, and safe.



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Appendix 1

Expert Advisory Group biographies

Jane Bawden, LLM (Hons) (Chair) (Auckland)

Jane is the CEO of Parent to Parent NZ, a support organisation for families living with disability. Prior to this she was a barrister and professional director, primarily in the health and disability services sector. She is also a trustee of Spectrum Care, a provider of services to people with disabilities. Jane is the mother of a young man who has a chromosomal disorder and autism spectrum disorder.

Teresa Wall, Director of Wall Consultants (Wellington)

Teresa Wall, Te Rarawa and Te Aupouri, is the Director of Wall Consultants, a company that provides equity policy advice to health agencies and works with non-government organisations on the design of health services and facilities. Before devoting her work full time to Wall Consultants, Teresa served as Deputy Director-General, Māori Health, and Acting Deputy Director-General Policy and Strategy in the Ministry of Health, New Zealand.

Teresa and her team in the Ministry of Health were known for:

1. Supporting the development of equity frameworks and tools
2. Publishing monitoring reports, e.g., Tatau Kahukura
3. Commissioning research reports, e.g., LiLACs (Life and Living in Advanced Age — cohort study), SAMMs (Sudden Acute Maternal Morbidity Study)
4. Publishing the first report on the health literacy status of New Zealanders — He Kōrero Mārama

Since establishing Wall Consultants, Teresa and a colleague, Michael McCarthy, have been project managing the building of a new medical centre for Ahuriri District Health (the settlement entity for the WAI 692 Napier Hospital and Health Services Waitangi Tribunal Claim). Teresa has also been providing advice to the Central Region DHB's Technical Advisory Service on how to strengthen the equity focus in the central DHB region services plan, and was commissioned by the Health Quality & Safety Commission to develop a blueprint for a Rangatahi Suicide report. Teresa is also the Chair of the Ora Toa Primary Health Organisation and the Capital & Coast DHB Māori Partnership Board.

Teresa has been very honoured and pleased to be part of the Expert Advisory Group established by the Health and Disability Commissioner.

Professor Alan Merry, Clinician and Researcher (Auckland)

Alan is an anaesthetist who practises in chronic pain management at Auckland City Hospital. He is Deputy Dean of the Faculty of Medical and Health Sciences, University of Auckland, Chair of the Board of the NZ Health Quality & Safety Commission, and a Board Member of the World Federation of Societies of Anaesthesiologists and Lifebox. His research and publications reflect interests in human factors and the role of the law in patient safety, and in global health. He is an Officer of the New Zealand Order of Merit and a Fellow of the Royal Society of New Zealand.

Dr Jeanne Snelling, Academic, Law and Bioethics (Dunedin)

Jeanne holds a joint appointment as a lecturer at the University of Otago in the Faculty of Law and the Bioethics Centre. Her research interests fall within the general health law field, as well as the regulation of new biotechnologies.

Dr Colin McArthur, Clinician and Researcher (Auckland)

Colin is an Intensive Care Specialist at Auckland City Hospital, and Clinical Advisor — Research for the Auckland District Health Board. Colin has made submissions on Right 7(4) in previous reviews of the HDC Act and Code.

Dr Brigit Mirfin-Veitch, Donald Beasley Institute (Dunedin)

Brigit is the Director of the Donald Beasley Institute, a non-profit organisation that specialises in intellectual disability (learning disability) research. Brigit is a sociologist who has been involved in research on a wide range of topics, including deinstitutionalisation, physical health, mental health and well-being, parenting and the law. She is also a Senior Research Fellow with the Centre for Postgraduate Nursing Studies (University of Otago). Brigit's PhD is in the social sciences ("Deinstitutionalisation in the lives of families of people with an intellectual disability").

Appendix 2

What should replace the “best interests” test? Options considered

Option	Description
Option 1 Status quo — best interests or net benefit	Retain best interests in the Code. A proportionate net benefit test that allows risk and burden to be weighed against potential benefit to the individual. No minimal risk threshold. Assumes social value and scientific merit conditions in NEAC guidelines have been met.
Option 2 No risk (or burden)	A risk-based test that sets an absolute threshold of no additional risk or burden to the person as a result of the research. Does not allow for, or require, individual benefit. Assumes social value and scientific merit conditions have been met.
Option 3 Minimal or negligible risk (and burden)	A risk-based test that sets an absolute threshold of no more than minimal foreseeable additional risk and burden to the person as a result of the research. Does not allow for, or require, individual benefit. Assumes social value and scientific merit conditions have been met.
Option 4 Individual benefit and minimal risk (and burden)	Two absolute tests requiring likelihood or potential individual benefit, and no more than minimal risk and burden. Not weighed against each other. Assumes social value and scientific merit conditions have been met.
Option 5 Various conditional and proportionate options	Different combinations possible, e.g., If there is no likelihood/potential of individual benefit (only social value), must be minimal risk but If there is likelihood/potential of individual benefit, no minimal risk threshold.
Option 6 Allow minor increase over minimal risk if compelling social value	A proportionate test that sets a minimal risk and burden threshold but allows a minor increase over minimal risk if the research is of very high social value.
Option 7 Not known to be contrary to best interests	

Pros	Cons
<ul style="list-style-type: none"> • Could allow research where there is potential benefit to the individual. 	<ul style="list-style-type: none"> • Individual benefits are speculative and an unrealistic test for research • No maximum risk threshold implied and no explicit focus on risk. Reliant on ethics guidelines to set risk threshold otherwise it is simply a net benefit assessment • Creates barriers to potentially valuable but low risk research.
<ul style="list-style-type: none"> • Provides the greatest level of protection for the individual • Would allow some research to happen that is currently unlawful, e.g., comparing two standard treatments where patients are randomised. 	<ul style="list-style-type: none"> • Would be a barrier to potentially valuable research with only a minimal increase in risk/burden.
<ul style="list-style-type: none"> • Provides more protection for individual by clearly specifying a maximum risk threshold • Takes away the need for individual benefits • Would allow low risk research. 	<ul style="list-style-type: none"> • Could exclude some research or participation in some research where there is a high chance of individual benefit but also high risk, which might be allowed under “best interests” or net benefit tests with no risk threshold • Appears “utilitarian”.
<ul style="list-style-type: none"> • Provides protection for individuals by clearly specifying a maximum risk threshold. 	<ul style="list-style-type: none"> • Individual benefits are speculative and an unrealistic test for research • Likely to result in focus on individual benefits and possible diversion of focus from risk.
<ul style="list-style-type: none"> • Possible flexibility. 	<ul style="list-style-type: none"> • Could be complex to implement • Lack of risk threshold in research with potential or likely individual benefit — becomes a net benefit or best interests test (see Option 1) • Social value may not be a minimum requirement.
<ul style="list-style-type: none"> • Could allow research that is of very high social value (higher than standard social value test). 	<ul style="list-style-type: none"> • Could be unacceptable as it appears to allow greater risk when benefits are to others, rather than to the individual — has the appearance of placing greater weight on society than the protection of the individual.
	<ul style="list-style-type: none"> • Does not have a strong risk focus • Complex to understand and implement • Benefits are speculative and unrealistic test for research.

Appendix 3

Should an individual risk assessment always be carried out? Options considered

Option	Description
Option 1 Yes, there should always be an individual assessment of risk and burden.	Decision-maker for individual enrolment should always ensure the foreseeable risks and burdens for that individual are minimal/negligible.
Option 2 No, an individual assessment of risk and burden isn't necessary if an ethics committee has decided the risk and burden overall are minimal/negligible.	Decision-maker for individual enrolment needs to ensure only that the study's inclusion/exclusion criteria for that individual have been met.
Option 3 Ideally there should be an individual assessment of risk and burden but it is not always practical:	
a. Allow someone to be enrolled without an individual risk and burden assessment in limited circumstances;	Acknowledges that in some circumstances an assessment of risk and burden might not be possible. At study approval stage, should be an explicit decision about whether the research can be approved knowing that individual assessments will not be possible.
OR	
b. Apply a lower risk threshold	In research where there is unlikely to be time to do an individual risk and burden assessment, a lower risk threshold should be applied than the usual test, e.g., no risk at all permitted.
AND	
c. Audit and reporting.	Require audit and reporting of research that has been approved to proceed without individual risk and burden assessment.

Pros	Cons
<ul style="list-style-type: none"> • Provides an additional safeguard • Able to take into account the circumstances of the individual to determine if risks and burdens of the research for that individual might be different from the general population. 	<ul style="list-style-type: none"> • Not always practical • Would restrict some research from happening, e.g., some emergency research.
<ul style="list-style-type: none"> • Efficient • Would allow research to proceed. 	<ul style="list-style-type: none"> • Not lawful under Right 7(4) • No additional safeguard • Not able to take into account the circumstances of the individual to determine if risks and burdens of the research for that individual might be different from the general population.
<ul style="list-style-type: none"> • Allows research to proceed in limited circumstances without an individual assessment of risk and burden. 	<ul style="list-style-type: none"> • Possible reduction in protections for that individual.
<ul style="list-style-type: none"> • Protects the individual from any risk of harm where there is no opportunity for individual assessment. 	<ul style="list-style-type: none"> • Could restrict how much research can be done, especially certain types of emergency research.
<ul style="list-style-type: none"> • Provides transparency and accountability where there has been less risk assessment. 	<ul style="list-style-type: none"> • Ethics committees would need additional powers and resources to do more monitoring and auditing • Additional costs for researchers.

Appendix 4

Who decides on individual enrolment? Options considered

Option	Description
Option 1 Status quo	AR can decide if permitted under PPPR Act. If no AR, provider decides as per the Code criteria: <ul style="list-style-type: none">• Best interests (or new)• Consistent with person's wishes OR• Views of other suitable persons taken into account
Option 2 Status quo with enhancements	AR can decide in all cases if PPPR Act amended. Risk-based test, consult with suitable persons, e.g., clinician, on risk assessment. If AR not available, provider decides as at present but with some enhancements: <ul style="list-style-type: none">• Ethics committee must require conflict of interest/perceived coercion to be managed if provider is the researcher• Expressions of dissent respected• Consult with other suitable persons• Other suitable persons have power of veto (on any grounds).
Option 3 New decision-maker	AR can decide in all cases if PPPR Act amended. New risk-based test, consult with suitable persons, e.g., consult person's clinician on risk assessment. If AR is not available, specify alternative decision-maker from provider, such as: <ul style="list-style-type: none">• Another provider not involved with the research• Family• Independent advocate• GP• Other

Pros	Cons
<ul style="list-style-type: none"> • Allows an AR who knows the person to make the decision if legally permitted and available • Opportunity to discuss prior wishes with AR in some instances, e.g., degenerative illness • Provider is likely to be most pragmatic option, especially in emergency research • Other suitable persons consulted. 	<ul style="list-style-type: none"> • AR unlikely to be available in many situations, especially emergency research • Provider could also be the researcher or closely associated with the researcher — potential conflict of interest • Most people are likely to want family involved but their role only consultation if available • Person’s wishes unlikely to be known or known with sufficient specificity to make a decision about research.
<ul style="list-style-type: none"> • As above, but conflict of interest must be dealt with • Gives greater weight to person’s own wishes • Greater role for other suitable persons — additional safeguard, research suggests people often want family to have a role in decision-making, veto acknowledges that families may have concerns of their own about research, acknowledges importance of collective decision-making for many families. 	<ul style="list-style-type: none"> • Person’s wishes unlikely to be known or known with sufficient specificity to make a decision about research • Expressions of dissent can be hard to interpret • Could be hard for families to make decisions under pressure (emergency research) • Hard to define “suitable persons” and could end up with a wide range of people with power of veto.
<ul style="list-style-type: none"> • Removes any potential for conflict of interest or coercion if the provider and researcher are the same person or closely aligned. 	<ul style="list-style-type: none"> • Hard to implement • No clear preferences from consultation process — all alternatives would have difficulties.

Appendix 5

What happens if it is not possible to consult other suitable persons during decision-making about individual enrolment? Options considered

Scenario 1: Barrier to consultation is related to the research — The study design/type of research means it is not likely to be possible to consult AR or other suitable persons in advance of enrolment, e.g., where there is a time constraint (some emergency research where intervention must start within a short time period). Because it is related to study design/type of research this is likely to be known at study approval stage.

Option	Description
Option 1 Do not proceed when consultation is not possible	In situations where it is not possible to consult with other suitable persons, do not allow the research to proceed OR Allow research to proceed but exclude those people for whom it is not possible to consult with someone else.
Option 2 Proceed without consultation	Allow the study to proceed and/or enrolment of individuals to proceed without consultation with other suitable persons if the researcher can demonstrate to the ethics committee that it would be difficult/impossible to consult others. ⁵⁰ Rely only on protocols and inclusion/exclusion criteria agreed by ethics committee and the provider's judgement about risk and burden.
Option 3 Proceed with enrolment but consult with suitable persons as soon as possible	Allow the study to proceed and enrol an individual according to protocols and inclusion/exclusion criteria agreed by ethics committee and provider's judgement about risk and burden. Consult suitable person as soon as possible; that person can withdraw the individual from the study if practicable (e.g., if individual is receiving an intervention it may not be appropriate to withdraw) or refuse individual's data to be used.
Option 4 In addition to options 2–3, audit and reporting of enrolments where no one else was consulted	As part of more proactive audit and monitoring of research involving adults unable to consent, include a specific requirement to report on research or cases where no one else was consulted on the enrolment, e.g., why it was not possible, what efforts were made, how soon suitable persons were informed and given the option to withdraw.

⁵⁰ It is assumed that if the requirement to consult other suitable persons is strengthened, this would need to be reflected in the study protocols and considered as part of the ethics committee approval process.

Pros	Cons
<ul style="list-style-type: none"> • Ensures someone known to the person always has input into the decision • Allows for consideration of expression of will and preference that other suitable persons know about. 	<ul style="list-style-type: none"> • Could make some research unviable, e.g., not a large enough sample size • Some emergency research would not be possible because time constraints make consultation impossible.
<ul style="list-style-type: none"> • Allows research to proceed. 	<ul style="list-style-type: none"> • No one known to the person has any input or opportunity to veto • Undermines principle that available suitable persons must be consulted.
<ul style="list-style-type: none"> • Provides transparency of decision-making and some greater protection of the individual • Allows for consideration of expression of will and preferences that other suitable persons know about • Provides some safeguards. 	<ul style="list-style-type: none"> • Could be too late to withdraw the person from the research (e.g., cannot stop or change treatment) • May relate only to ongoing use of data.
<ul style="list-style-type: none"> • Provides transparency around decision-making where others have not been consulted. 	<ul style="list-style-type: none"> • Ethics committees would need additional powers and resources to do more monitoring and auditing • Additional costs for researchers.

Scenario 2: Barrier to consultation is related to the person — The person does not have anyone else who could be consulted in advance or at any other time, e.g., someone in a dementia unit or with a severe intellectual disability who has no AR and no suitable person to consult. Not likely to be related to the study design/type of research so unlikely to know in advance at study approval stage that there will be no suitable person to consult for an individual.

Option	Description
<p>Option 1 Approve study but do not proceed with individual enrolment without consultation</p>	<p>Study can be approved but individuals cannot be enrolled if they have no suitable person to consult.</p>
<p>Option 2 Approve study and proceed with enrolment without consultation</p>	<p>Study can be approved and individuals can be enrolled without consulting any suitable person. Rely only on protocols and inclusion/exclusion criteria agreed by ethics committee and the provider’s judgement about risk and burden.</p>
<p>Option 3 Approve study and seek independent advocate for an individual where no one else can be consulted</p>	<p>Study can be approved but no one can be enrolled without consultation with suitable person unless an independent advocate has had the opportunity to veto enrolment.</p>
<p>Option 4 In addition to options 2–3, audit and reporting of enrolments where no one else was consulted</p>	<p>As part of more proactive audit and monitoring of research involving adults unable to consent, include a specific requirement to report on research or cases where no one else was consulted on the enrolment, e.g., why it was not possible, why it was necessary to recruit someone who had no one to consult, what efforts were made to recruit other participants where someone could be consulted.</p>

Pros	Cons
<ul style="list-style-type: none"> • Allows the research to proceed involving people who do have someone to consult • Ensures someone known to the person always has input into the decision • Allows for consideration of expression of will and preferences that other suitable persons know about. 	<ul style="list-style-type: none"> • May make it more difficult or take longer to recruit required sample size, but will not necessarily make the research unviable because other people with the condition who have a suitable person to consult can be recruited.
<ul style="list-style-type: none"> • Allows research to proceed. 	<ul style="list-style-type: none"> • No one known to the person has any input or opportunity to veto • Could make this group a convenient research population • This group is unable to complain and may have no one to complain on their behalf • Undermines principle that other suitable persons must be consulted.
<ul style="list-style-type: none"> • Allows research to proceed • Provides additional safeguard for the person. 	<ul style="list-style-type: none"> • No one known to the person has any input or opportunity to veto • Could be costly and cause delay. Need to consider if this would be best use of resources.
<ul style="list-style-type: none"> • Provides transparency around decision-making where others have not been consulted. 	<ul style="list-style-type: none"> • Ethics committees would need additional powers and resources to do more monitoring and auditing • Additional costs for researchers.

Appendix 6

Strengthening ethics review and approval — Options considered

All options assume NEAC guidelines are updated to consolidate guidance relating to research with adults unable to consent, and that principles relating to study approval are amended in line with Table 6.

Option	Description
Option 1 Status quo with some enhancements	<p>HDECs continue to review and approve health and disability research with adults unable to consent, with some enhancements:</p> <p>All research is considered by an HDEC — amend SOP provisions regarding Masters level and below; remove distinctions between interventional and observational research and do full review for all research.</p> <p>Mandate HDECs to carry out more monitoring, follow-up, and audit of research with adults unable to consent (e.g., audit where there has not been consultation with other suitable persons before enrolment).</p>
Option 2 Option 1 plus specialist panel to provide expert advice to HDECs for health and disability research with adults unable to consent, especially on risk assessment	<p>HDECs provide review and approval of research with adults unable to consent, with enhancements as above plus establish a new national specialist panel to provide independent expert advice to HDECs, particularly on risk assessment.</p>
Option 3 Specialist ethics committee	<p>Establish a single specialist ethics committee to review and approve all research with adults unable to consent, with access to expertise to assess all relevant aspects of proposals, and mandate for greater monitoring, follow-up, and audit.</p>

Pros	Cons
<ul style="list-style-type: none"> • Closes some gaps so that research not currently being considered by an HDEC is reviewed • Greater scrutiny and transparency. 	<ul style="list-style-type: none"> • Some additional resources required for increased monitoring and follow-up • Does not provide robust and independent assessment of risk or other aspects of these research studies • Unclear how much additional work there would be for HDECs and impact on time available to consider proposals.
<ul style="list-style-type: none"> • As above • Provides a clear focus on risk and independent support to HDECs on risk assessment • Allows a critical mass of knowledge to be developed, especially regarding risk assessment. 	<ul style="list-style-type: none"> • Additional resources required for increased monitoring and follow-up, and establishment of a specialist panel • Unclear how much additional work there would be for HDECs and impact on time available to consider proposals • If focus is primarily on risk assessment, would not necessarily build critical mass of expertise around all aspects of research with adults unable to consent • Advisory only.
<ul style="list-style-type: none"> • Provides greatest level of protection for participants • Clear pathway • Allows a critical mass of knowledge to be developed regarding ethics of research with adults unable to consent. 	<ul style="list-style-type: none"> • Resource implications.

Appendix 7

Legislative instruments and options for the Code

Internationally, some other countries have stand-alone legislation relating to people with mental incapacity, which include provisions for research. There are also various sets of research ethics guidelines produced by professional bodies (e.g., Helsinki⁵¹, CIOMS⁵²), which include comprehensive provisions for non-consensual research. Some other countries have codes of consumer rights, not all of which are legally binding like New Zealand's.

Stronger and more consistent legislative backing for the core principles outlined in this report is preferable. Further discussion would be needed about the level of detail to go into legislation, as some submitters have argued that legislation should set an enabling framework for ethics but not try to legislate too rigidly for ethical principles. This allows for some flexibility and the ability to consider different contexts. It also implies a system where different instruments such as the legislative framework, ethics guidelines, and operating procedures for ethics committees work together as a coherent whole.

Table 6 sets out some broad options for providing a suitable legislative base for a set of principles for research involving adults unable to consent. There are pros and cons to all of the options. Right 4(2) of the Code gives the NEAC guidelines some legislative backing for research that is covered by the Code. However, approval of the NEAC guidelines or changes would not require parliamentary approval, so relying on Right 4(2) is not as robust as some other legislative options.

51 "Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects", World Medical Association, July 2018.

52 "International Ethical Guidelines for Health-related Research Involving Humans", CIOMS, 2016.

Stand-alone legislation could be introduced similar to the England and Wales Mental Capacity Act or the Adults with Incapacity (Scotland) Act. This would be ideal but may not be pragmatic. There are options about whether the focus of the legislation would be on all health and disability research with research with adults unable to consent as a section; or whether the focus of the legislation would be on incapacity with research as a section.

Closely related to this are options about what should happen to the Code, ranging from amendments to the existing Right 7(4), a new right within the Code for research, a completely new Code focused on research, or removing research from the Commissioner's mandate completely (see Table 7).

[See tables overleaf >>](#)

Table 6: Legislative options — How to give effect to the principles for doing health and disability research with adults unable to consent

- All options assume provisions relating to decisions about enrolling individuals remain in the Code as a minimum.
- All options assume at least some amendments to the Code, e.g., requirement for ethics committee approval, change “best interests” test.

Option	Description
Option 1 Status quo	Continue to have some principles in law (Code and PPPR Act) and some in ethics guidelines, with amendments as above.
Option 2 All principles in Code	Include all principles for research involving adults unable to consent in Code — this includes provisions relating to both study approval and enrolment of individuals.
Option 3 Amend existing or proposed legislation or regulations	Include all principles in existing or proposed legislation or in regulations to existing or proposed legislation, e.g., Therapeutic Products Bill, PPPR Act.
Option 4 New stand-alone legislation	Develop new legislation that contains all principles for research involving adults unable to consent.
Option 5 Enforce NEAC guidelines through Right 4(2)	NEAC guidelines are ethical standards and are covered by Right 4(2) of the Code. Failure to comply with ethical standards could therefore be a breach of the Code.

Pros	Cons
<ul style="list-style-type: none"> • Low cost. 	<ul style="list-style-type: none"> • Does not meet objectives of improving safeguards by giving more teeth to principles • Principles are in different places — some have legal mandate and some do not.
<ul style="list-style-type: none"> • Principles are all in one place • Commissioner can make the recommendations. 	<ul style="list-style-type: none"> • Would require a lot of detail in the Code and would be disproportionate to other sections • Would undermine a key strength of the Code, which is its simplicity and brevity.
<ul style="list-style-type: none"> • Pragmatic — gives legislative mandate but does not require new legislation to be passed • Inclusion in PPPR Act regulations would be simplest option and consistent with purpose of the Act re mental incapacity. 	<ul style="list-style-type: none"> • Does not fit well in Therapeutic Products Bill — could cause ongoing confusion and lack of transparency (hard to find) • Would require Justice to take the lead if using PPPR Act as the vehicle. Unlikely to be appetite for further changes to PPPR Act • Could imply Justice is responsible for research involving adults unable to consent.
<ul style="list-style-type: none"> • Principles are all in one place • Simplicity and transparency • Clarity of legal position. 	<ul style="list-style-type: none"> • Not likely to be appetite for new legislation.
<ul style="list-style-type: none"> • Provides legislative mandate to principles for study approval for research with adults unable to consent (principles for individual enrolment remain in the Code) • Does not require legislative change. 	<ul style="list-style-type: none"> • Principles that are not also in the Code could be more easily amended and weaken protections again • Could imply HDC is responsible for enforcement of all principles • Does not provide complete coverage as the Code applies only to research carried out by providers.

Table 7: Format of Code changes — How should the Code itself be changed to reflect the proposed changes?

Options 1–4 assume rights relating to individual enrolment remain in the Code, at a minimum. Depending on legislative options in Table 6, other principles relating to study approval might also be included in the Code. Options 1–4 assume requirement for ethics committee approval is incorporated similar to Right 7(10)(b).

Option	Description
<p>Option 1 Status quo with amended wording</p>	<p>Leave Right 7(4) as is but amend the wording to reflect a new test and any other changes agreed.</p>
<p>Option 2 Amend Right 7(4) or develop a sub-clause for research in Right 7(4)</p>	<p>Amend Right 7(4) to incorporate a new sub-clause that is specific to research — depends on the extent of changes needed.</p> <p>For example, Right 7(4)(a) might read: "... it is in the best interests of the consumer, or, in the case of research, the research has received the approval of an ethics committee and there is no more than minimal foreseeable risk and no more than minimal burden to the consumer from participating in the research."</p>
<p>Option 3 Develop a new separate right for research in the Code</p>	<p>Develop a stand-alone right for research in the Code and remove from Right 7(4).</p>
<p>Option 4 Develop a new Code specifically for research</p>	<p>A parallel Code could be developed that sets out rights in relation to research.</p>
<p>Option 5 Remove research from the Code</p>	<p>Change the focus of the Code so that it no longer covers research, and include all principles in another instrument (e.g., ethics guidelines or alternative legislation).</p>

Pros

Cons

- Potentially minimises changes needed — would allow targeted changes to be made but other relevant clauses to remain unchanged.

- Simply changing the wording could mean that the changes also apply to services — the “best interests” test is the right test where someone is receiving services so should not be a blanket change.

- Could reduce conflation of treatment and research in the Code
- Could allow for expansion of Code coverage in relation to research so that all health and disability research is covered by the Code regardless of who carries it out.

- Could be confusing if provisions relating to research end up being significantly different from provisions for services — i.e., if there are more changes than just to the “best interests” test as proposed in the main principles table.

- Could reduce conflation of treatment and research in the Code
- Could allow for expansion of Code coverage in relation to research so that all health and disability research is covered by the Code regardless of who carries it out (i.e., expand coverage of HDC).

- Disproportionate as other rights also apply to research, so they would all need to be repeated
- Would reduce simplicity and brevity of the Code.

- Research and treatment could become too disconnected.

- Creates significant separation between treatment and research, which is not always possible or desirable
- Could reduce protections for consumers in relation to health and disability research, which was the origin of the establishment of HDC and the Code, or avenue for complaint.



