HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

HDC Consultation Document

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

24 February 2017

Published by
Health & Disability Commissioner
Level 11
Technology One House
86 Victoria Street
PO Box 11934
Wellington 6142
New Zealand.

Phone: 04 494 7900
Fax: 04 494 7901
E-mail: hdc@hdc.org.nz

Contents

Commissioner's foreword

This consultation paper seeks your views on health and disability research involving adult consumers who are unable to consent to their participation in that 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. New Zealand law permits research to be conducted with such consumers as participants only in limited circumstances. We want to know whether you think any changes should be made to the current law.

New Zealand law has a strong focus on the rights of consumers. Our Code of Health and Disability Services Consumers' Rights (the Code) gives legally enforceable rights to all consumers of health and disability services, and places corresponding obligations on providers of those services.

The Code came into force in 1996, following an inquiry led by Judge Dame Silvia Cartwright into cervical cancer research conducted at National Women's Hospital. The research involved withholding treatment from women with cervical abnormalities without their knowledge or consent. The publication of the findings of the inquiry (the Cartwright Report) was a watershed moment in the history of New Zealand's health and disability sector. The Cartwright Report led to a number of reforms aimed at ensuring the protection of consumers' rights, including the introduction of the Code.

The Code turned 20 in July 2016. Throughout those 20 years, New Zealand has been a leader in the field of rights for people who receive health and disability services. Respect for the autonomy of consumers, and the expectation of transparency from providers, are fundamental principles that underlie the Code. Most obviously, those principles can be seen in the right to make an informed choice and give informed consent before receiving health and disability services. However, they also underpin many of the other rights in the Code, and are deeply engrained within the culture of our health and disability sector. These principles must be kept front and centre when considering whether the law relating to non-consensual research should be changed.

It is difficult to decide where to draw the line regarding what research is appropriate if the participants are unable to give consent. Consumers who are unable to make informed decisions for themselves are particularly vulnerable to abuses of their rights and interests. The Code must continue to protect consumers from such abuses. However, research with such participants could lead to significant advances in the care we are able to provide to them or to other similar consumers in the future.

The existing law in New Zealand allows studies to proceed in relation to participants who are unable to consent

if participation in the research is in their "best interests". The nature of research is that the outcomes are uncertain, so it is difficult to assess the potential risks and benefits for the consumer participants.

The Code and the ideas it embodies are well embedded in the New Zealand environment. I will not recommend any change to the current laws unless I believe there is a necessity to do so. To help me determine whether there is a need for change, I have decided to undertake a thorough public consultation. I look forward to receiving a wide range of views on this complex and important issue.

Anthony Hill
Health and Disability Commissioner

Introduction

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

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

The Health and Disability Commissioner undertakes regular reviews of the Code, during which members of the public are invited to comment on the need for any amendments. The most recent review occurred in 2013–2014. Only two submissions were received on the issue of non-consensual research. One submission supported an amendment to Right 7(4) that would allow a greater number of studies involving incompetent[1] participants to proceed, while the other opposed any change to the current law.

Recently, it has been argued that New Zealand's laws regarding non-consensual research are too restrictive, and prohibit studies that could lead to significant improvements in health and disability services. It has been suggested that research conducted on consumers who cannot give informed consent may 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, in some cases, that information may not be obtainable through research involving only competent consumers. Some research can be conducted only with incompetent participants, and the findings from the research have the potential to save lives in the future. This is demonstrated by *Case Study D (adrenaline)* on page 23.

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

---

[1] *The Code of Health and Disability Services Consumers' Rights refers to consumers who are "competent" and "not competent". In this consultation document, consumers who are unable to give consent are referred to as "not competent", "incompetent" or "lacking capacity to give consent".*

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended?

The New Zealand population includes many different people and cultures. It is made up of people who are indigenous (Māori) and people from other countries, including the Pacific Islands. As a result, in New Zealand there are different ethnicities with a wide range of religious and cultural practices, values and beliefs.

People who lack the capacity to give informed consent come from all cultural, ethnic and religious backgrounds. It is important for everyone to have access to the benefits of research. At the same time, it is important to protect their rights.

Like other people, there will be some Māori who will not be able to make informed choices and give informed consent. The Treaty of Waitangi principles of partnership, participation and protection are useful for informing engagement with Māori to ensure appropriate research outcomes.

We value the engagement and input to this process from different groups, and we want to hear the views of all New Zealanders during this consultation.

A glossary in **Appendix D** on page 62 explains the meaning of commonly used terms in this document.

Expert Advisory Group

This paper has been prepared with the assistance of an Expert Advisory Group. Members of the Group were appointed to advise and assist the Commissioner in relation to the review, including on the creation of this consultation paper. The Group members are:

1. **Jane Bawden, Barrister (Auckland)**

   Ms Bawden is a lawyer. She holds a variety of governance appointments in the health and disability sector. She is the mother of a young adult with significant disabilities.

2. **Dr Colin McArthur, Clinician and Researcher (Auckland)**

   Dr McArthur is an Intensive Care Specialist at Auckland City Hospital. He is also Clinical Advisor — Research for the Auckland District Health Board.

3. **Professor Alan Merry, Clinician and Researcher (Auckland)**

   Professor Merry practises in anaesthesia and chronic pain management at Auckland City Hospital. He is also the Head of the School of Medicine at the University of Auckland, and Chair of the Board of the NZ Health Quality and Safety Commission.

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

   Dr Mirfin-Veitch is the Director of the Donald Beasley Institute, a non-profit organisation that specialises in learning (intellectual) disability research.

5. **Dr Jeanne Snelling, Academic, Law and Bioethics (Dunedin)**

   Dr Snelling is an adjunct lecturer in the Otago University Faculty of Law, and currently has a three-year Fellowship as a Research Fellow in Bioethics and Health Law.

6. **Teresa Wall, former Deputy Director-General, Ministry of Health (Wellington)**

   Ms Wall, who is from Te Rarawa and Te Aupouri, was a senior civil servant and was for many years the Deputy Director-General for Te Kete Hauora (the Māori Health Business Unit) at the Ministry of Health.

How can you contribute?

We want to hear your views on whether the law relating to research involving adult consumers who are unable to give consent should be kept as it is currently. If you think a change is needed, we want to know what you think that change should look like.

Please note that this consultation is limited to research involving **adult** consumers. If, at the conclusion of the consultation process, the Commissioner decides to recommend any change to the law, further consultation will be conducted before that change is implemented. If the proposed change has the potential to affect research involving children, comments on such research will be welcomed at that stage.

How to send us your views

We are seeking views from all interested people, including consumers, persons interested in the welfare of incompetent people (such as family/whānau), providers, and researchers.

You will find the consultation document and submission form at *www.hdc.org.nz*. Submissions close on 30 April 2017.

What happens next?

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received. The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. As noted above, if any change to the Code is recommended, further consultation will be conducted.

What is in this Consultation Document?

Part I outlines the scope of the consultation.

Part II sets out the current law and key principles that apply when determining whether research can be conducted on adult consumers who do not have competence to give consent.

Part III considers the requirements in some other countries.

Part IV provides some case studies to illustrate the issues.

Part V sets out the specific issues and questions on which we are seeking public input.

A glossary of the meaning of key terms referred to in this paper is included in **Appendix D.**

Part I: Scope of this consultation

This part outlines who and what this consultation is about. It describes the nature of the consumers who are the subject of the consultation and provides an outline of the types of research those consumers could be enrolled in.

Who are we talking about?

This consultation relates only to **adult** consumers who are unable to provide informed consent to participate in research. 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.[2] 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.[3]

These rights mean that just because consumers have cognitive impairments or difficulty communicating, it should not necessarily be concluded that they are unable to make informed choices. Researchers must make all reasonable efforts to support consumers with diminished competence to enable them to give, or decline to give, informed consent.

Some consumers will be unable to make an informed choice and consent to participate in research. People in this group may include:

- Consumers who are unconscious at the time the research is conducted, for example consumers who are in a coma.
- Consumers with significant cognitive impairments who are unable, despite special assistance, to make or communicate an informed choice about participating in research, for example consumers who have a significant intellectual disability or have advanced dementia.

---

[2] *Right 7(2).*

[3] *Right 7(3).*

What are we talking about?

This consultation relates to health and disability research with incompetent adult participants.

Health and disability research includes any scientific investigation that aims to generate knowledge about a health or disability issue that can be applied in the future. It is sometimes difficult to distinguish research from treatment.

In general, treatment is a service provided to a person that is intended to improve that person's health. Research aims to generate knowledge. All the circumstances of the service are relevant when making a decision as to whether research is taking place. Sometimes treatment will contain episodes that can be termed research: for example a series of procedures may yield new knowledge that can be generalised.[4]

The Code provisions relate to health and disability research conducted only by a health care or disability services provider, which means an institution or person providing health or disability services. Research relating to health and disability issues conducted by non-providers, for example, some academic research, may not be within the jurisdiction of the Commissioner.

Categories of research

Broadly speaking, there are two types of health and disability research: interventional studies and observational studies.

Interventional studies

In interventional studies, the researcher intentionally alters the care or services provided to the participants for the purpose of adding to our knowledge of the health effects of the intervention.

Example: Dr Jones wants to test a new medication to treat cancer. She gathers a group of research participants and (with their informed consent) randomly assigns each one to receive either the new medication or a placebo.[5] She monitors the participants for several months. Dr Jones is conducting an interventional study, because she has controlled the treatment provided (or not provided) to the participants in order to allow her to study the effects of the new cancer medication in comparison with the placebo.

Interventional studies can be either **therapeutic** or **non-therapeutic.** Non-therapeutic studies are studies in which the intervention will not provide any direct benefit to the participants.
Example: Dr Jones wants to gather information about the possible risks and side-effects of the new cancer treatment

---

[4] *See the discussion in 11HDC01072 available at www.hdc.org.nz.*

[5] *A placebo is a simulated or otherwise medically ineffective treatment, such as a sugar pill.*

before she trials it on consumers with cancer. She does an initial trial using healthy participants. As the participants in the trial do not have cancer, they are not expected to receive any therapeutic benefit from the trial. The trial is therefore non-therapeutic.

Therapeutic studies, on the other hand, are studies in which the intervention being studied may provide a direct benefit to some of the research participants.

Example: Dr Jones next conducts a trial of the new medication on consumers with cancer. This new trial is a therapeutic study. While there is no guarantee of benefit to any particular consumer, the intervention being studied may provide a therapeutic benefit to the consumers involved in the research, as they have the cancer that the medication is intended to treat.

Observational studies

Like interventional studies, observational studies may involve looking at the effects of interventions provided to human participants. However, in observational studies, researchers do not control the interventions — they study only interventions that would have been provided to participants regardless of participation in the study.

Example: The medication used in Dr Jones' research has been approved and has become a standard treatment option for cancer. She wants to collect information about the effects of the new treatment (treatment A) in comparison with another standard treatment for cancer (treatment B). She identifies 50 consumers who have been prescribed treatment A and 50 consumers who have been prescribed treatment B. She asks all 100 consumers to fill out a questionnaire about their experiences. Dr Jones is conducting an observational study. She has not altered the treatment provided to the participants, as each participant had already been prescribed one of the two medications. She is simply gathering information about the effects of those medications.

Observational studies may still require interventions in order to collect data. In the above example, those interventions took the form of questionnaires administered to the participants. Information collection can in some instances be more intrusive, for example, where blood needs to be taken or muscle biopsies are required.

Observational studies may also include some qualitative research, for example, research that involves studying people in their own environment through the use of methods such as observing and interviewing participants. The Code applies only if the research is carried out by a health or disability services provider.

Observational studies are designed to help people in the future. In most cases they do not provide any benefit to individual participants, because they are just about collecting data.

Part II: Research on adult incompetent participants — key principles and current law

This part sets out the key principles and current law that apply when determining whether research can be conducted on adult consumers who are unable to give consent to their participation. It includes review of research by ethics committees.

Key principles

The following principles are particularly relevant to the issues in this consultation paper.

1. Consumer autonomy (consumers making informed choices about their participation in research)

Consumer autonomy is at the heart of the requirement of informed consent, and relates to the ability of people to make their own decisions. As stated above, the principle is sometimes expressed as "nothing about us without us". A research participant is an autonomous human being, possessing all fundamental rights and deserving full respect.[6] People have different preferences and priorities, and the decision one person makes about participating in research may be different from the decision another person would make in the same circumstances. The significance of consumer autonomy — and the importance of maximising that autonomy to the greatest extent possible — is paramount when considering the law governing research with participants who are unable to give consent.

2. Protection of vulnerable consumers

Consumers who lack the capacity to make informed choices as to whether or not they wish to participate in research are particularly vulnerable to abuses of their rights and interests.

Frequently there is some level of risk faced by consumers as a result of their participation in health and disability research. The level of risk will change depending on the type of research in question and the specifics of the study. Involvement in research may also

[6] *The conditions necessary for research that will be respectful of ethical principles were defined in the Nuremberg Code (1947): "The voluntary consent of the human subject is absolutely essential."*

involve some level of burden imposed on the participants. For example, they may undergo procedures, testing and monitoring additional to what would be required for standard treatment. These procedures could cause pain or discomfort. If the research has participants who are unable to give informed consent, the risk may be greater because they may also be unable (or less able) to complain, communicate symptoms, or express distress during the study. Accordingly, it is important that the law in relation to research involving such consumers provides safeguards against any potential abuse of their rights and interests.

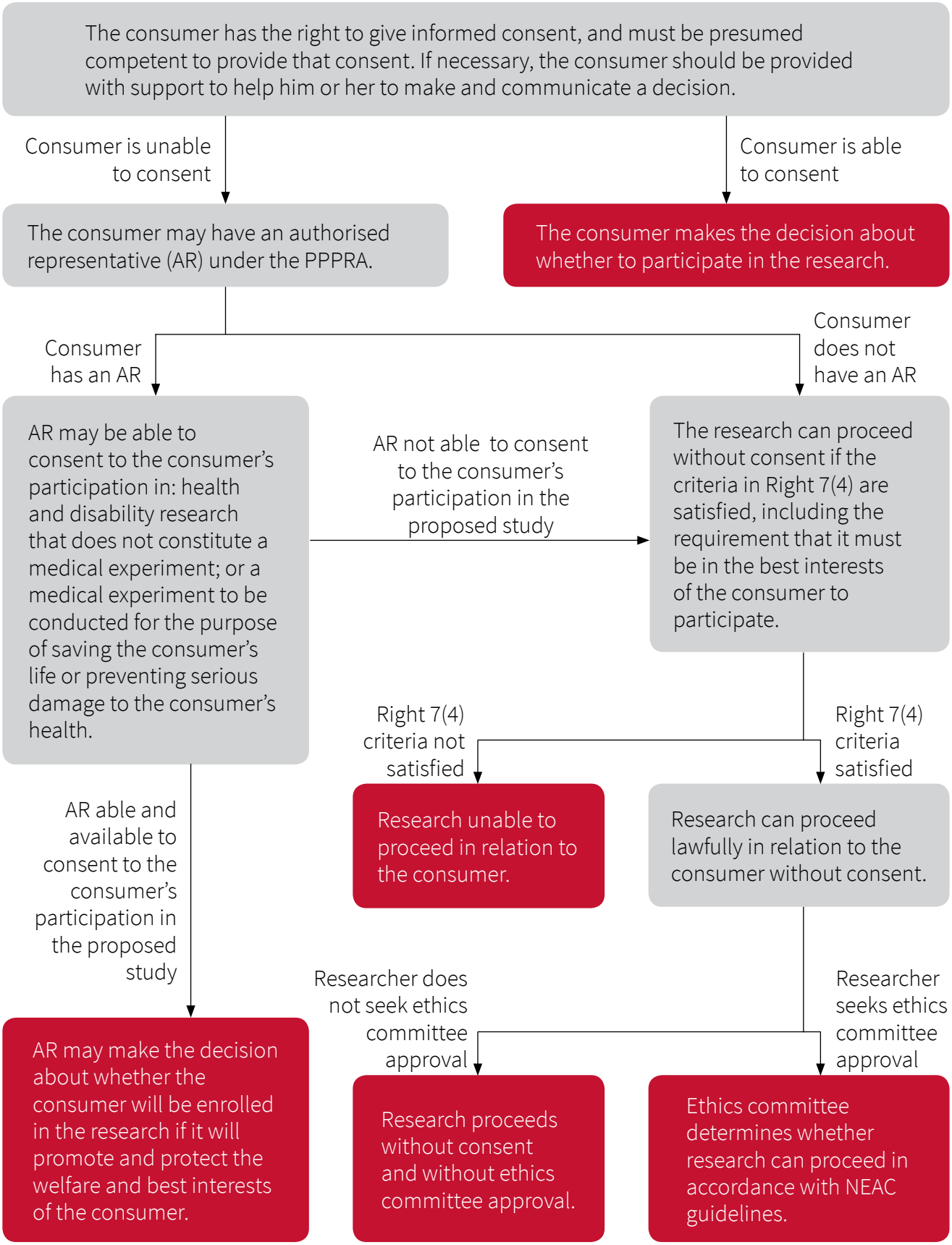
The current position

New Zealand law and ethical guidelines

This section sets out New Zealand's laws and ethical guidelines in relation to health and disability research involving participants who are unable to provide informed consent. It also outlines some relevant international instruments that apply, to differing extents, in New Zealand.

A visual representation of New Zealand's legal and ethical framework is included at Figure 1.

Figure 1: New Zealand's legal and ethical framework (excluding court orders and advance consent)



Informed consent

New Zealand Bill of Rights Act 1990

The New Zealand Bill of Rights Act 1990 provides that every person has the right not to be subjected to medical or scientific experimentation without that person's consent,[7] and that everyone has the right to refuse to undergo any medical treatment.[8]

The Code of Health and Disability Services Consumers' Rights (the Code)

The right to give informed consent before receiving health or disability services is fundamental to the Code. Right 7(1) states:

> 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 this Code provides otherwise.

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

If a consumer is to be enrolled in a research project, he or she must consent both to the health or disability services provided, and to his or her data being used for research purposes. In order for a consumer to provide valid informed consent to participate in health and disability research, a number of elements must be satisfied:

- The consumer must be provided with the information that a reasonable consumer would expect to receive in the consumer's circumstances. This will include an explanation of the options available to the consumer, information about any risks or side-effects of those options, and whether the proposed research requires and has received ethical approval.[9]
- The information must be communicated effectively in a form, language and manner that enables the consumer to understand it. The environment should enable both the consumer and the provider to communicate openly, honestly and effectively.[10]

---

[7] *New Zealand Bill of Rights Act 1990 (NZBORA), section 10.*

[8] *NZBORA, section 11.*

[9] *Code of Health and Disability Services Consumers' Rights (the Code), Right 6.*

[10] *The Code, Right 5.*

- Once the consumer has been informed appropriately, he or she must provide written informed consent to participate in the research.[11]
- A consumer may refuse consent or withdraw consent to participate in research at any time.[12]

Advance consent

Where consumers are aware that they may become unable to give informed consent to participate in research, they may choose to give advance consent to participate in the research while they still have capacity to do so. This prior consent is known as an advance directive.[13] For example, a consumer with early dementia who wishes to be enrolled in an upcoming clinical trial could, while he or she still has capacity, consent by way of advance directive in case the consumer's condition progresses to the point where he or she does not have capacity by the time of enrolment in the research.

There is no limit on how far ahead of time an advance directive can be made, but at the time the consumer makes the advance directive he or she must be able to foresee the circumstances that will arise and have sufficient information about the research to be able to make an informed choice to participate. Assuming that these factors have not changed by the time the research starts, then the advance directive will be sufficient consent for the consumer to be enrolled in the research.

Delayed (retrospective) consent

Delayed consent refers to situations in which research is conducted with incompetent participants who later regain capacity. Once they have regained capacity they are asked to give retrospective consent to the research already conducted. In New Zealand, delayed consent is not a legally valid form of informed consent.[14] It is not possible to provide informed consent retrospectively, because the events have already taken place, even if the consumer, upon regaining capacity, does not have an objection to having been included in the research.[15]

---

[11] *The Code, Right 7(6)(a).*

[12] *The Code, Right 7(7).*

[13] *Right 7(5) of the Code states: "Every consumer may use an advance directive in accordance with the common law."*

[14] *See Right 7(1) of the Code.*

[15] *A person can consent to the future use of data held about him or her.*

When can incompetent consumers be research participants?

Adult consumers who cannot make informed choices can be enrolled in research only if one of the below circumstances is satisfied.

Consent on behalf of a consumer who does not have competence to make an informed choice

A person who is not competent to give consent may have a welfare guardian appointed by the Court with the power to make decisions about the person's personal care and welfare. Alternatively, while competent, the person may have appointed someone to make decisions on his or her behalf should he or she become incompetent in the future. The appointed person is called an attorney, and is authorised to act by an activated Enduring Power of Attorney (EPOA). In this paper, a person who has been given relevant authority through his or her appointment as a welfare guardian or under an EPOA is referred to as the "authorised representative".

The first and paramount consideration of an authorised representative is the promotion and protection of the welfare and best interests of the incompetent person.[16] This requirement is closely aligned to the best interests requirement in Right 7(4) of the Code.

The authorised representative may consent to the consumer's participation in a medical experiment only if the experiment is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health. The term "medical experiment" is not defined in the Protection of Personal Property and Rights Act 1988 (PPPRA), and its meaning has not yet been considered by the New Zealand courts.

If the purpose of the research is to generate generalisable knowledge to benefit people in the future rather than saving the consumer's life or preventing serious damage to the consumer's health, then the authorised representative is unable to consent to the incompetent person's participation.

If the health and disability research does not involve a medical experiment, for example, observing and analysing the way in which caregivers communicate with people with advanced dementia, the authorised representative may be able to consent to the incompetent person's participation.

The authorised representative is required to consult with the incompetent person so far as is possible, and also consult with others interested in the person's welfare and competent to advise the authorised representative in relation to the personal care and welfare of that person.[17]

---

[16] *Protection of Personal Property and Rights Act 1988 (PPPRA), section 18(3).*

[17] *PPPRA, section 18(4).*

Court order

The Family Court may make an order that an incompetent person be provided with specified kinds of medical advice or treatment, which could, for example, be to receive a medication that is available only via a clinical trial.[18]

What happens if there is no person entitled to consent and no court order?

If there is no person entitled to give consent on behalf of the consumer, and a Court has not made an order in relation to the research proposed, the consumer may not be a research subject unless the criteria in Right 7(4) of the Code are satisfied.

Right 7(4) of the Code

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 where:

a. it is in the best interests of the consumer; and

b. reasonable steps have been taken to ascertain the views of the consumer; and

c. 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.

Best interests

People presenting at an Emergency Department or admitted to an Intensive Care Unit commonly do not have an activated EPOA or a welfare guardian appointed by the Court. Other incompetent people (such as people with intellectual impairments) may have authorised representatives but, as discussed, the power of such representatives to consent to a medical experiment is limited.

As a result, researchers who wish to conduct research with incompetent participants may rely on Right 7(4) of the Code to enrol participants without consent, in which case participation must be in the **best interests** of the consumer. Right 7(4) requires a case-by-case assessment of whether it is in

[18] *PPPRA, section 10(f).*

the best interests of each individual consumer to be enrolled in the proposed research. In some cases, this will involve a clinical assessment by the provider of the consumer's treatment; however, it may also involve taking a broader view of the consumer's needs, interests, and quality of life, as required by Right 4(4) of the Code.[19]

Generally, the decision-maker would weigh the benefits and disadvantages of participating in the research against the benefits and disadvantages of the consumer's best alternative to participation.

Non-therapeutic research will seldom pass the best interests test, because in most cases there is no expected benefit to the participants. However, sometimes there may be an **inclusion** benefit, which is where a consumer benefits from being enrolled in research because he or she receives better monitoring and care than is received through standard care, or is helped by participating in a qualitative research process, such as an interview. An inclusion benefit is an indirect flow-on effect of being involved in research, rather than a direct effect of the particular treatment provided. Despite this, it may be a relevant factor.

Few therapeutic studies (i.e., studies in which there is at least some possibility of direct benefit to the participants) would satisfy the best interests test, because of the uncertainty of the risks and benefits.

In addition, it is common to use placebo groups or control groups in research. The participants allocated to those groups are unlikely to receive any direct benefit from participation in the research.

The best interests test does not provide for any consideration of the potential for advances in knowledge that may benefit other people. 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.

Ethics approval

In addition to the requirements in the law set out above, research proposals may be considered by ethics committees. There are a number of institutional ethics committees, for example within universities. Some District Health Boards also have ethics approval processes.

Research in New Zealand may be

[19] *Right 4(4) states: "Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer."*

assessed by a Health and Disability Ethics Committee (HDEC). HDECs apply ethical guidelines to reach decisions about whether particular studies should be allowed to proceed. There is no legal requirement for human research to obtain approval from an HDEC. However, HDEC approval is often necessary for a research project to obtain funding or for research results to be published.

When an application for ethics approval is made in relation to a particular study, the relevant HDEC must be satisfied that the study is lawful. While HDECs are not responsible for ensuring the legality of research (that responsibility lies with the researcher), they may require the researcher to obtain legal advice confirming that the research is legal before proceeding. If the study is deemed to be lawful, the HDEC will assess whether the proposed research meets the ethical guidelines set out by the National Ethics Advisory Committee (NEAC). The relevant parts of the NEAC guidelines are set out in **Appendix C.**

Relevant international law and guidelines

The principles underlying New Zealand's legal and ethical framework, including the importance of informed consent, reflect the principles found in relevant international law and guidelines. New Zealand must comply with such instruments and guidelines to the extent that they have been incorporated into New Zealand law. Key examples are set out in **Appendix B.**

Part III: What are other countries doing?

The issues in this paper have been considered in other countries. This section outlines the key provisions in the United Kingdom and Australia.

The United Kingdom and Australia allow research involving participants who are unable to give consent to proceed in a broader range of circumstances than in New Zealand.

Further key provisions from the UK and Australia are set out in **Appendix A.**

United Kingdom

In England and Wales the law recognises that the interests of others is an important consideration in determining whether to proceed with research on people who are unable to give consent. The Code of Practice for the Mental Capacity Act 2005 states:

> It is important that research involving people who lack capacity can be carried out, and that it is carried out properly. Without it, we would not improve our knowledge of what causes a person to lack or lose capacity, and the diagnosis, treatment, care and needs of people who lack capacity.

While accepting the importance of allowing research to be carried out, the interests of patients are presumed to take precedence over the interests of science and society in conducting research. The researcher must be able to show that it is necessary to enrol in the project people who are unable to consent, because research of a similar nature could not be carried out on people who are capable of deciding to participate.

Research can take place on people who lack the capacity to consent only if that research:

Either

- has the potential to benefit the participant without creating a disproportionate risk

or

- is intended to provide knowledge of the causes or treatment of, or care of, people affected by a similar condition. If so, researchers must have good reason to believe that any risks to individual participants are negligible, will not significantly impact their freedom or privacy, and will not be unduly invasive or restrictive.

The Mental Capacity Act 2005 and the Code of Practice provide a number of additional safeguards to protect vulnerable consumers, including requiring that research:

- is part of a project that has received formal approval;
- cannot be carried out in contravention of an advance directive; and
- cannot be carried out (or continued) if a participant objects or appears to object.

In Scotland, the Adults with Incapacity (Scotland) Act 2000 provides for similar safeguards. However, in Scotland:

- Research cannot be carried out on a person who is unable to consent (whether or not that person is likely to receive a benefit) unless the research entails no foreseeable or only a minimal foreseeable risk to a participant.

In England, Wales and Scotland, further additional safeguards apply where the proposed research involves clinical trials for new medicines, including that the person's legal representative has given informed consent to the person's participation in the trial, and that the trial relates to a condition that affects the participant.

Australia

In Australia, there is a strong focus on ascertaining and promoting the rights of people to choose whether to participate in research. The National Health and Medical Research Council (NHMRC) has published guidelines for ethical conduct in human research. The guidelines relating to people with a cognitive impairment, intellectual disability or mental illness require that prior to conducting research, researchers should inform Human Research and Ethics Committees how they propose to determine capacity (including how the decision will be made and by whom, criteria used, and process for reviewing capacity during the research).

If it is proposed to conduct research on a person who does not have capacity to consent, researchers must obtain consent from a person who is authorised to consent on the incompetent person's behalf. Consent should be witnessed by a person who has the capacity to understand the merits, risks and procedures of the research and is independent of the research team, and who knows the person and is familiar with his or her condition. Where consent is sought by a proxy, the researcher should still explain to the participant as far as possible what the research is about. Any refusal or reluctance to participate should be respected.

Part IV: Case studies

The following case studies illustrate some types of research that could not proceed without the participants' informed consent under current New Zealand law. Some of the studies are based on actual research applications made in New Zealand or overseas (although the details may have been simplified and/or altered), and some are hypothetical. The questions asked in relation to each case study are intended to help us understand what factors are important to you and where you believe the line should be drawn. It may help you to imagine that you or someone you care about is a potential participant in each study. Considering these examples may assist you to form your views about the consultation questions in Part IV.

Please note that the questions in this paper are reproduced in the **Consultation Response Form** on the HDC website (*www.hdc.org.nz*). To provide us with your comments, either complete the form online or print the form, record your answers on the form and return it to PO Box 11934, Wellington 6142.

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

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

The study

Dr A wants to study how quickly antibiotics used to treat septic[20] patients in Intensive Care Units (ICUs) are removed by dialysis. It is already known that most antibiotics are removed by dialysis to some extent, but the rate can vary. Consumers with severe sepsis often require dialysis therapy due to acute

[20] *Sepsis is a serious illness. It happens when the person's body has an overwhelming immune response to an infection.*

kidney injury. A special form of dialysis is used for these consumers in the ICU, but currently there is no information available regarding the rate at which that form of dialysis removes the antibiotics used to treat sepsis. If antibiotics are cleared by dialysis at a faster rate than expected, the sepsis could be undertreated.

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

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

Case Study A questions

A.1

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

Yes/No/Unsure

A.2

Please give the reasons you formed this view.

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

The study

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

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

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

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

Case Study B questions

B.1

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

Yes/No/Unsure

B.2

Please give the reasons you formed this view.

B.3

What are your views about "delayed consent"?

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

The study

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

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

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

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

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

Case Study C questions

C.1

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

Yes/No/Unsure

C.2

Please give the reasons you formed this view.

Case Study D: Clinical trial regarding use of adrenaline

The study

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

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

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

To deal with this issue, Dr D suggests an "opt-out" process for consent. Consumers not wishing to be enrolled in the study would be able to opt out by

requesting a bracelet with "NO STUDY" engraved on it. Awareness of the study would be raised through a public information campaign.

Case Study D questions

D.1

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

Yes/No/Unsure

D.2

Please state the reasons you formed this view.

D.3

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

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

The study

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

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

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

for the research participants, the effect would be temporary because the drug would not be available to participants after the conclusion of the trial.

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

Case Study E questions

E.1

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

Yes/No/Unsure

E.2

Please state the reasons you formed this view.

E.3

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

Yes/No/Unsure

E.4

Please state the reasons you formed this view.

Part V: Consultation

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

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

As stated above, please note that the questions in this paper are reproduced in the **Consultation Response Form** on the HDC website: *www.hdc.org.nz*. To provide us with your comments, please either complete the form online or print the form, record your answers on the form and return it to PO Box 11934, Wellington 6142.

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

General comments

Consultation Question 1

1.1
Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent?

Yes/No/Unsure

If **yes,** please state the reasons why.

If **no,** please state the reasons why not.

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

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

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

Yes/No/Unsure

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

Consultation Question 2

Dissent

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

2.1

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

Yes/No/Unsure

2.2

Please give reasons for your answer.

Consultation Question 3

Delayed consent

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

3.1

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

Yes/No/Unsure

3.2

Please give reasons for your answer.

Consultation Question 4

Alternative participants

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

4.1

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

Yes/No/Unsure

4.2

Please make any further comments you have about question 4.1.

Consultation Question 5

Interests of others to be taken into account

The current law in New Zealand takes account of the interests of only the incompetent research participant and not the interests of others, such as other people with the same condition.

Example

Dr C's proposed research (*Case Study C — Dementia care*) may not provide any benefit to the participants (those who receive standard care may not receive any benefit from inclusion and it is not known whether person-centred care will be a benefit). However, the findings from the research may benefit consumers with dementia in the future.

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

- be permitted only if it may benefit others who have the same or a similar condition to the participant
- be connected to the impairing condition that prevents the participants from being able to provide consent

- be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent
- be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.

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

5.1

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

Yes/No/Unsure

5.2

Please give reasons for your answer.

If the answer to question 5.1 is **yes:**

5.3

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

Yes/No/Unsure

5.4

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

1.

2.

3.

4.

5.

Any others?

Consultation Question 6

Ethics committee approval

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

6.1	6.2
Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent? **Yes/No/Unsure**	Please give reasons for your answer.

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

The current law incorporates consideration of risk, burden and benefit (also referred to as advantages and disadvantages[21]) to the proposed research participants. Right 7(4) of the Code requires that participation in the research is in the participant's best interests. The PPPRA[22] provides that the paramount consideration for an authorised representative is the welfare and best interests of the incompetent person.

A precise assessment of the advantages and disadvantages of participation in proposed research will not be possible because the outcome of the research is not known at the time the participants are enrolled.

Set out below are some possible alternative ways of assessing the advantages and disadvantages of research for participants. Please note that the options provided are not an exhaustive list.[23] You may wish to suggest your own way of assessing advantages and disadvantages on the Consultation Response Form.

---

[21] *In this document, "disadvantages" means the risks and/or the burdens of the research.*

[22] *Protection of Personal and Property Rights Act 1988; see discussion at page 13.*

[23] *See, for example, Joanna Manning, "Non-Consensual Clinical Research in New Zealand: Law Reform Urgently Needed" (2016) 23 JLM 516 and Alison Douglass, Mental Capacity: Updating New Zealand's Law and Practice (Report for the New Zealand Law Foundation, Dunedin, July 2016) www.lawfoundation.org.nz*

Balancing tests — would the consumer be better off participating in the research than not participating?

The "best interests" test is a balancing test — it requires the decision-maker to balance the effects on the consumer of participating in the research against the effects of not participating.

None of Case Studies A–E as described can proceed under a "best interests" test:

- Neither *Case Study A (sepsis)* nor *Case Study B (neurosurgery)* has any potential to benefit the participants.
- In *Case Study C (dementia)*, the disadvantages of participating in the study are unknown. More information would first be needed about whether potential benefit to the participants outweighs the possible disadvantages of "person-centred care".
- In *Case Study D (adrenaline)*, the disadvantages of participation likely outweigh the potential benefit to the participants.
- In *Case Study E (Down syndrome)*, the risks associated with the study drug outweigh the potential benefit to the participants.

The "best equal interests" test — would the consumer benefit as much from participating as from not participating?

A "best equal interests" test would be likely to allow research comparing the effectiveness of two standard treatments, so, for example:

- *Case Study B (neurosurgery)* would likely be allowed to proceed. The current evidence does not indicate that either of the study products is better than the other, and the consumer would receive treatment using one of the products anyway. While the consumers would not benefit from being enrolled in the research and randomly allocated to receive treatment using one of the two products, it would also not be contrary to their interests. The risks and benefits of participating and not participating are equal, and so the consumer could be enrolled in Dr B's study under a "best equal interests" test.
- *Case Study C (dementia)* might be allowed to proceed only if researchers could show that the possible disadvantages of "person-centred care" are the same as, or no worse than, the potential benefit to the participants.
- *Case Studies A (sepsis)*, *D (adrenaline)* and *E (Down syndrome)*, however, would still not be permitted to proceed.

Should the proposed research have the potential to benefit the participant without imposing on the participant a burden that is disproportionate to that potential benefit?

In relation to the case studies above, under this test:

- *Case Studies A (sepsis)* and *B (neurosurgery)* would not be permitted to proceed, as the proposed research does not have the potential to benefit the participants.
- *Case Study C (dementia)* might be allowed to proceed, depending on the precise assessment of the potential risks, burdens and benefits of the study (in particular, whether the possible risks and burdens of "person-centred care" outweigh its potential benefit to the participants).
- *Case Study D (adrenaline)* would probably not be permitted to proceed, as the burden and potential risks of participation likely outweigh the potential benefit to the participants.
- *Case Study E (Down syndrome)* would probably not be allowed to proceed, as the risks associated with the study drug outweigh the potential benefit to the participants.

Threshold tests

An alternative to using a balancing test is to incorporate thresholds into the law. Threshold tests do not require any weighing of factors, they simply provide a minimum threshold or maximum threshold of advantage and disadvantage. In the research context, these thresholds would require that participation in the research:

- provides a potential advantage to the consumer that meets a specified minimum threshold (for example, a substantial benefit or a real and direct benefit);
- does not pose a greater risk to the consumer than a specified maximum threshold (for example, minimal risk or negligible risk); and
- does not impose a greater burden on the consumer than a specified maximum threshold (for example, minimal discomfort or the research cannot be unduly invasive or restrictive).

The types of research that would be permitted using threshold tests would depend on the interpretation of the thresholds adopted. However, as an illustration, let us assume that the law

is changed to include the following thresholds:

- There must be a reasonable expectation that participation in the research will provide a direct benefit to the consumer.
- The research must involve no more than minimal foreseeable risk to the consumer.
- The research must involve no more than minimal discomfort to the consumer.

Using those thresholds:

- *Case Studies A (sepsis)* and *B (neurosurgery)* would not be permitted to proceed, as there is no reasonable expectation that participation in the research would provide a direct benefit to the consumer.
- *Case Study C (dementia)* might be permitted to proceed, depending on the assessment of the potential risks, burdens and benefits of person-centred care.
- *Case Studies D (adrenaline)* and *E (Down syndrome)* would not be permitted to proceed, as they involve more than minimal foreseeable risk to the consumer.

Risk and burden thresholds, but no benefit threshold

A more permissive option would be to adopt maximum risk and burden thresholds but no benefit threshold, meaning it would not be necessary for participation to provide any direct benefit to the consumer. This option would allow low-risk observational research and most research comparing two standard treatments.

The removal of the benefit threshold would allow *Case Studies A (sepsis)* and *B (neurosurgery)* to proceed.

Some overseas models include different tests depending on whether or not the research provides a direct benefit to the consumer participants. If the research will not benefit the consumer it may proceed in some circumstances, but there are additional criteria. For example, the Adults with Incapacity (Scotland) Act 2000 requires that:[24]

> Where the research is not likely to produce real and direct benefit to the adult, it may nevertheless be carried out if it will contribute through significant improvement in the scientific understanding of the adult's incapacity to the attainment of real and direct benefit to the adult or to other persons having the same incapacity.

[24] *Adults with Incapacity (Scotland) Act 2000, section 51(4)*

Consultation Question 7

7.1

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

Yes/No/Unsure

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

7.2

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

7.3

Please state the reasons you formed this view.

Consultation Question 8

Who decides?

At present, if proposed research includes participants who are unable to consent for themselves, the decision as to whether an incompetent consumer can participate in the research will be made by one of the following:

- An EPOA or welfare guardian (if the research is not a medical experiment or if it is a medical experiment to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health).
- The Court (if a personal order has been made).
- The provider of health and/or disability services (who must determine whether the requirements of Right 7(4) have been satisfied). If the provider is unable to ascertain the views of the consumer, the provider must take into account the views of suitable persons interested in the welfare of the consumer (e.g., family members).

8.1

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

Yes/No/Unsure

8.2

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

Yes/No/Unsure

8.3

If you answered **"Yes"** to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making. Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

Person who could have a role in decision-making (X)	Should X ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?	If yes, in what circumstances should X be involved in decision-making? i.e., **a.** In all cases where X is available? **b.** Only when particular criteria are met (e.g., that the study is to be conducted for the purpose of saving the consumer's life or preventing serious damage to the consumer's health)? **c.** Only when other possible decision-makers (please specify which decision-makers) are unavailable? **d.** Only where the circumstances require that an urgent decision is needed (e.g., *Case Study D — adrenaline*)? **e.** Other? Please choose the letter(s) for any of the options above that you think should apply, or provide comment if you prefer.	Where X is involved in decision-making, what role should he or she have? i.e., **a.** Consulted by decision-maker? **b.** Power to veto* consumer's participation in the research? **c.** Provide or withhold consent on behalf of the consumer? **d.** Other? Please choose the letter(s) for any of the options above that you think should apply, or provide comment if you prefer. ** A veto means the right to refuse or reject permission for an incompetent consumer's participation in research.*
EPOAs and welfare guardians	**Yes/No/Unsure**		
Family/ whānau	**Yes/No/Unsure**		
Provider not involved in the research (e.g., consumer's responsible clinician or GP)	**Yes/No/Unsure**		
Researcher	**Yes/No/Unsure**		
Other (please name):	**Yes/No/Unsure**		

8.4

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

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

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

1.

2.

3.

4.

5.

8.5

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

Final comments

Reform of the law governing research involving consumers who are unable to give consent could include amendment of Right 7(4) of the Code, the creation of a new "research-specific" right in the Code, amendment of the Protection of Personal Property and Rights Act 1988 (PPPRA) and/or the creation of new legislation specifically addressing this topic. At this stage, however, we are seeking input only regarding what provisions you believe should be contained in the law, not where in the law those restrictions should be located (e.g., in the Code or in legislation).

The Commissioner's jurisdiction relates primarily to the Code. The Health and Disability Commissioner Act 1994 allows the Commissioner to recommend specific Code changes to the Minister of Health directly. Should an amendment to the Act or Code be proposed, further consultation on the amendment would be required. However, the various parts of New Zealand's regulatory framework in relation to research involving competent consumers are interconnected. If, following this consultation, the Commissioner decides to suggest changes outside of the Code, the relevant Ministry will consider whether those changes should be made and, if so, the form they should take.

The inclusion of options for legal reform in this consultation paper does not indicate that the Commissioner will recommend a change to the law. As discussed above, the current law is designed to maximise consumer autonomy and provide protection for vulnerable consumers. The Commissioner will recommend changing the law only if he considers that there are compelling reasons to do so. He is equally interested in receiving views in favour of the current law and views in favour of reform.

The options for legal reform are included because it may be difficult to decide whether there should be changes without examining what that change might be. These are intended to help you decide whether you think the law should stay the same or be changed and, if you favour change, what you think that change should look like.

If there are any comments or suggestions you would like to make but have not been able to (i.e., comments or suggestions that do not relate to any of the questions above), please include them in the final box in the Consultation Response Form.

Appendix A: What are other countries doing?

Research involving consumers who do not have capacity to give consent is currently permitted in broader circumstances in the United Kingdom and Australia than in New Zealand. This appendix provides relevant excerpts from the legislation and ethical guidelines of those jurisdictions.

Mental Capacity Act 2005 (England and Wales)

The Mental Capacity Act 2005 (MCA) applies to anyone in England or Wales involved in the care, treatment and support of people aged 16 years and over who are unable to make some or all decisions for themselves. The MCA does not apply to non-observational clinical trials of investigational medical products, which are instead subject to the Medicines for Human Use (Clinical Trials) Regulations 2004. In relation to other research, however, the following provisions apply.

30 Research

1. Intrusive research carried out on, or in relation to, a person who lacks capacity to consent to it is unlawful unless it is carried out—
   a. as part of a research project which is for the time being approved by the appropriate body for the purposes of this Act in accordance with section 31, and
   b. in accordance with sections 32 and 33.
2. Research is intrusive if it is of a kind that would be unlawful if it was carried out—
   a. on or in relation to a person who had capacity to consent to it, but
   b. without his consent.
3. A clinical trial which is subject to the provisions of clinical trials regulations is not to be treated as research for the purposes of this section.

3A. Research is not intrusive to the extent that it consists of the use of a person's human cells to bring about the creation in vitro of an embryo or human admixed embryo, or the subsequent storage or use of an embryo or human admixed embryo so created.

3B. Expressions used in subsection (3A) and in Schedule 3 to the Human Fertilisation and Embryology Act 1990 (consents to use or storage of gametes, embryos or human admixed embryos etc.) have the same meaning in that subsection as in that Schedule.

4. "Appropriate body", in relation to a research project, means the person, committee or other body specified in regulations made by the appropriate authority as the appropriate body in relation to a project of the kind in question.

5. "Clinical trials regulations" means—

   a. the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) and any other regulations replacing those regulations or amending them, and

   b. any other regulations relating to clinical trials and designated by the Secretary of State as clinical trials regulations for the purposes of this section.

6. In this section, section 32 and section 34, "appropriate authority" means—

   a. in relation to the carrying out of research in England, the Secretary of State, and

   b. in relation to the carrying out of research in Wales, the National Assembly for Wales.

31 Requirements for approval

1. The appropriate body may not approve a research project for the purposes of this Act unless satisfied that the following requirements will be met in relation to research carried out as part of the project on, or in relation to, a person who lacks capacity to consent to taking part in the project ("P").

2. The research must be connected with—

   a. an impairing condition affecting P, or

   b. its treatment.

3. "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.

4. 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 capacity to consent to taking part in it.

5. The research must—

   a. have the potential to benefit P without imposing on P a burden that is disproportionate to the potential benefit to P, or

b. be intended to provide knowledge of the causes or treatment of, or of the care of persons affected by, the same or a similar condition.

6. If the research falls within paragraph (b) of subsection (5) but not within paragraph (a), there must be reasonable grounds for believing—
   a. that the risk to P from taking part in the project is likely to be negligible, and
   b. that anything done to, or in relation to, P will not—
      i. interfere with P's freedom of action or privacy in a significant way, or
      ii. be unduly invasive or restrictive.
7. There must be reasonable arrangements in place for ensuring that the requirements of sections 32 and 33 will be met.

32 Consulting carers etc.

1. This section applies if a person ("R")—
   a. is conducting an approved research project, and
   b. wishes to carry out research, as part of the project, on or in relation to a person ("P") who lacks capacity to consent to taking part in the project.
2. R must take reasonable steps to identify a person who—
   a. otherwise than in a professional capacity or for remuneration, is engaged in caring for P or is interested in P's welfare, and
   b. is prepared to be consulted by R under this section.
3. If R is unable to identify such a person he must, in accordance with guidance issued by the appropriate authority, nominate a person who—
   a. is prepared to be consulted by R under this section, but
   b. has no connection with the project.
4. R must provide the person identified under subsection (2), or nominated under subsection (3), with information about the project and ask him—
   a. for advice as to whether P should take part in the project, and
   b. what, in his opinion, P's wishes and feelings about taking part in the project would be likely to be if P had capacity in relation to the matter.
5. If, at any time, the person consulted advises R that in his opinion P's wishes and feelings would be likely to lead him to decline to take part in the project

(or to wish to withdraw from it) if he had capacity in relation to the matter, R must ensure—

a. if P is not already taking part in the project, that he does not take part in it;

b. if P is taking part in the project, that he is withdrawn from it.

6. But subsection (5)(b) does not require treatment that P has been receiving as part of the project to be discontinued if R has reasonable grounds for believing that there would be a significant risk to P's health if it were discontinued.

7. The fact that a person is the donee of a lasting power of attorney given by P, or is P's deputy, does not prevent him from being the person consulted under this section.

8. Subsection (9) applies if treatment is being, or is about to be, provided for P as a matter of urgency and R considers that, having regard to the nature of the research and of the particular circumstances of the case—

a. it is also necessary to take action for the purposes of the research as a matter of urgency, but

b. it is not reasonably practicable to consult under the previous provisions of this section.

9. R may take the action if—

a. he has the agreement of a registered medical practitioner who is not involved in the organisation or conduct of the research project, or

b. where it is not reasonably practicable in the time available to obtain that agreement, he acts in accordance with a procedure approved by the appropriate body at the time when the research project was approved under section 31.

10. But R may not continue to act in reliance on subsection (9) if he has reasonable grounds for believing that it is no longer necessary to take the action as a matter of urgency.

33 Additional safeguards

1. This section applies in relation to a person who is taking part in an approved research project even though he lacks capacity to consent to taking part.

2. Nothing may be done to, or in relation to, him in the course of the research—

a. to which he appears to object (whether by showing signs of resistance or otherwise) except where what is being done is intended to protect him from harm or to reduce or prevent pain or discomfort, or

b. which would be contrary to—

i. an advance decision of his which has effect, or

ii. any other form of statement made by him and not subsequently withdrawn, of which R is aware.

3. The interests of the person must be assumed to outweigh those of science and society.

4. If he indicates (in any way) that he wishes to be withdrawn from the project he must be withdrawn without delay.

5. P must be withdrawn from the project, without delay, if at any time the person conducting the research has reasonable grounds for believing that one or more of the requirements set out in section 31(2) to (7) is no longer met in relation to research being carried out on, or in relation to, P.

6. But neither subsection (4) nor subsection (5) requires treatment that P has been receiving as part of the project to be discontinued if R has reasonable grounds for believing that there would be a significant risk to P's health if it were discontinued.

34 Loss of capacity during research project

1. This section applies where a person ("P")—

a. has consented to take part in a research project begun before the commencement of section 30, but

b. before the conclusion of the project, loses capacity to consent to continue to take part in it.

2. The appropriate authority may by regulations provide that, despite P's loss of capacity, research of a prescribed kind may be carried out on, or in relation to, P if—

a. the project satisfies prescribed requirements,

b. any information or material relating to P which is used in the research is of a prescribed description and was obtained before P's loss of capacity, and

c. the person conducting the project takes in relation to P such steps as may be prescribed for the purpose of protecting him.

3. The regulations may, in particular,—

a. make provision about when, for the purposes of the regulations, a project is to be treated as having begun;

b. include provision similar to any made by section 31, 32 or 33.

The Medicines for Human Use (Clinical Trials) Regulations 2004 (United Kingdom)

The Medicines for Human Use (Clinical Trials) Regulations 2004 apply to all non-observational clinical trials of investigational medical products across the United Kingdom. The Regulations contain specific provisions for adults who are incapable of giving informed consent to participate in research, as set out below.

Schedule 1

PART 5

CONDITIONS AND PRINCIPLES WHICH APPLY IN RELATION TO AN INCAPACITATED ADULT

Conditions

1. The subject's legal representative has had an interview with the investigator, or another member of the investigating team, in which he has been given the opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.
2. The legal representative has been provided with a contact point where he may obtain further information about the trial.
3. The legal representative has been informed of the right to withdraw the subject from the trial at any time.
4. The legal representative has given his informed consent to the subject taking part in the trial.
5. The legal representative may, without the subject being subject to any resulting detriment, withdraw the subject from the trial at any time by revoking his informed consent.
6. The subject has received information according to his capacity of understanding regarding the trial, its risks and its benefits.
7. The explicit wish of a subject who is capable of forming an opinion and assessing the information referred to in the previous paragraph to refuse participation in, or to be withdrawn from, the clinical trial at any time is considered by the investigator.
8. No incentives or financial inducements are given to the subject or their legal representative, except provision for compensation in the event of injury or loss.

9. There are grounds for expecting that administering the medicinal product to be tested in the trial will produce a benefit to the subject outweighing the risks or produce no risk at all.
10. The clinical trial is essential to validate data obtained—
    a. in other clinical trials involving persons able to give informed consent, or
    b. by other research methods.
11. The clinical trial relates directly to a life-threatening or debilitating clinical condition from which the subject suffers.

Principles

12. Informed consent given by a legal representative to an incapacitated adult in a clinical trial shall represent that adult's presumed will.
13. The clinical trial has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the cognitive abilities of the patient.
14. The risk threshold and the degree of distress have to be specially defined and constantly monitored.
15. The interests of the patient always prevail over those of science and society.

Adults with Incapacity (Scotland) Act 2000

The Adults with Incapacity (Scotland) Act 2000 provides a framework for safeguarding the welfare of people in Scotland, aged 16 years or over, who lack capacity. The Act sets out specific provisions for adults who are incapable of giving informed consent to participate in research. The Medicines for Human Use (Clinical Trials) Regulations 2004 also apply, as stated in section 51(3A) of the Act.

51 Authority for research

1. No surgical, medical, nursing, dental or psychological research shall be carried out on any adult who is incapable in relation to a decision about participation in the research unless—
    a. research of a similar nature cannot be carried out on an adult who is capable in relation to such a decision; and
    b. the circumstances mentioned in subsection (2) are satisfied.

2. The circumstances referred to in subsection (1) are that—
    a. the purpose of the research is to obtain knowledge of—
        i. the causes, diagnosis, treatment or care of the adult's incapacity; or
        ii. the effect of any treatment or care given during his incapacity to the adult which relates to that incapacity; and
    b. Subject to subsection (3A), the conditions mentioned in subsection (3) are fulfilled.
3. The conditions are—
    a. the research is likely to produce real and direct benefit to the adult;
    b. the adult does not indicate unwillingness to participate in the research;
    c. the research has been approved by the Ethics Committee;
    d. the research entails no foreseeable risk, or only a minimal foreseeable risk, to the adult;
    e. the research imposes no discomfort, or only minimal discomfort, on the adult; and
    f. consent has been obtained from any guardian or welfare attorney who has power to consent to the adult's participation in research or, where there is no such guardian or welfare attorney, from the adult's nearest relative.

3A. Where the research consists of a clinical trial of a medicinal product, the research may be carried out—
    a. without being approved by the Ethics Committee, if a favourable opinion on the trial has been given by an ethics committee, other than the Ethics Committee, in accordance with regulation 15 of the Medicines for Human Use (Clinical Trials) Regulations 2004;
    b. without the consent of any guardian or welfare attorney, or the adult's nearest relative, if—
        i. it has not been practicable to contact any such person before the decision to enter the adult as a subject of the clinical trial is made, and
        ii. consent has been obtained from a person, other than a person connected with the conduct of the clinical trial, who is—

A. the doctor primarily responsible for the medical treatment provided to that adult, or

B. a person nominated by the relevant health care provider.

c. without the consent of any guardian or welfare attorney, or the adult's nearest relative, if—

i. treatment is being, or is about to be, provided for an adult who is incapable in relation to a decision about participation in the research as a matter of urgency;

ii. having regard to the nature of the clinical trial and of the particular circumstances of the case it is necessary to take action for the purposes of the clinical trial as a matter of urgency;

iii. it has not been reasonably practicable to obtain the consent of any such person;

iv. it has not been reasonably practicable to obtain the consent of any of the persons mentioned in paragraph (b)(ii)(A) or (B); and

v. the action to be taken is carried out in accordance with a procedure approved by the Ethics Committee or any other ethics committee or by an appeal panel appointed under Schedule 4 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) at the time it gave its favourable opinion in relation to the clinical trial.

4. Where the research is not likely to produce real and direct benefit to the adult, it may nevertheless be carried out if it will contribute through significant improvement in the scientific understanding of the adult's incapacity to the attainment of real and direct benefit to the adult or to other persons having the same incapacity, provided the other circumstances or conditions mentioned in subsections (1) to (3) are fulfilled.

5. In granting approval under subsection (3)(c), the Ethics Committee may impose such conditions as it sees fit.

6. The Ethics Committee shall be constituted by regulations made by the Scottish Ministers and such regulations may make provision as to the composition of, appointments to and procedures of the Ethics Committee and

may make such provision for the payment of such remuneration, expenses and superannuation as the Scottish Ministers may determine.

7. Regulations made by the Scottish Ministers under subsection (6) may prescribe particular matters which the Ethics Committee shall take into account when deciding whether to approve any research under this Part.

8. In this section any reference to—

   a. a guardian shall include a reference to a guardian (however called) appointed under the law of any country to, or entitled under the law of any country to act for, an adult during his incapacity, if the guardianship is recognised by the law of Scotland;

   b. a welfare attorney shall include a reference to a person granted, under a contract, grant or appointment governed by the law of any country, powers (however expressed) relating to the granter's personal welfare and having effect during the granter's incapacity.

9. In this section—

"clinical trial on a medicinal product" means a clinical trial as defined by regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004;

"an ethics committee" has the meaning given by that regulation;

"person connected with the conduct of the trial" and "relevant health care provider" have the meanings given by Schedule 1 to those regulations.

National Statement on Ethical Conduct in Human Research (2007) (Australia)

The National Statement on Ethical Conduct in Human Research is a series of guidelines that ethics committees in Australia will take into account when approving research involving consumers who are unable to give consent. The National Statement is not legally enforceable, although compliance is generally required in order for researchers to obtain funding for their studies.

Chapter 4.4: People highly dependent on medical care who may be unable to give consent

Introduction

Medical care increasingly offers interventions or treatment for people at times of serious risk to their life or wellbeing. These risks may be temporary or permanent. People can become highly dependent on those interventions and treatments and may be incapable of comprehending their situation or of communicating about it. At the same time, research on those interventions and treatments is necessary to assess and improve their efficacy.

This chapter describes conditions under which research involving people highly dependent on medical care might proceed although their capacity to give consent is limited or non-existent.

In every instance, relevant jurisdictional laws will need to be taken into account.

Significant ethical issues are raised by research conducted in the following settings:

- neonatal intensive care;
- terminal care;
- emergency care;
- intensive care; and
- the care of unconscious people.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8, except where that research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review.

Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.

Guidelines

Research merit and integrity

4.4.1 Research involving people who are highly dependent on medical care may be approved where:

a. it is likely that the research will lead to increased understanding about, or improvements in, the care of this population;

b. the requirements of relevant jurisdictional laws are taken into account; and

c. either:

   i. any risk or burden of the proposed research to this particular participant is justified by the potential benefits to him or her; or

   ii. where participants have capacity to consent, any risk or burden is acceptable to them and justified by the potential benefits of the research.

Justice

4.4.2 People highly dependent on medical care may be exposed to severe threats to their lives, so that recruiting them into research might seem unfair. However, those people are entitled to participate in research and, when the conditions of paragraph 4.4.1 are met, their involvement is not unfair.

Beneficence

4.4.3 The distinguishing features of *neonatal intensive care research* are the small size and unique developmental vulnerability of the participants and the potential for very long-range impact on their growth, development and health. In this research, risks and potential benefits should be assessed with particular care by individuals or groups with relevant expertise.

4.4.4 The distinguishing features of *terminal care research* are the short remaining life expectancy of participants and their vulnerability to unrealistic expectations of benefits. Terminal care research should be designed so that:

a. the benefits of research to individual participants or groups of participants, or to others in the same circumstances, justify any burden, discomfort or inconvenience to the participants;

b. the prospect of benefit from research participation is not exaggerated;

c. the needs and wishes of participants to spend time as they choose, particularly with family members, are respected; and

d. the entitlement of those receiving palliative care to participate is recognised.

Respect

4.4.5 People involved in research to which this chapter applies may have impaired capacity for verbal or written communication. Provision should be made for them to receive information, and to express their wishes, in other ways.

4.4.6 In *emergency care research*, recruitment into a research project often has to be achieved rapidly. Where the research involves emergency treatment and meets the requirements of 4.4.1, consent for the research may be waived provided the conditions of paragraph 2.3.6 are satisfied.

4.4.7 In *intensive care research*, heavy sedation may impair participants' cognition, and communication is difficult with people receiving ventilatory assistance. Whenever possible, consent to intensive care research, based on adequate information, should be sought from or on behalf of potential participants before admission to that level of treatment. When prior consent to research is not possible, the process described in paragraphs 4.4.9 to 4.4.14 should be followed.

4.4.8 In *research with unconscious people*, the participants cannot be informed about the research and their wishes cannot be determined. Those who are unconscious should be included only in minimally invasive research, or in research designed both to be therapeutic for them and to improve treatment for the condition from which they suffer.

Process to be followed

4.4.9 Consent should be sought from people highly dependent on medical care wherever they are capable of giving consent and it is practicable to approach them.

4.4.10 Where it is not practicable to approach a person highly dependent on medical care, or the person is not capable of making such a decision, consent should be sought from the participant's guardian, or person or organisation authorised by law, except under the circumstances described in paragraph 4.4.13.

4.4.11 When consent is to be sought, either from the potential participant or another on his or her behalf, steps should be taken to minimise the risk that:

stress or emotional factors may impair the person's understanding of the research or the decision to participate; and

the dependency of potential participants and their relatives on the medical personnel providing treatment may compromise the freedom of a decision to participate.

4.4.12 Where the researcher is also the treating health professional, it should be considered whether an independent person should make the initial approach and/or seek consent from potential participants or from others on their behalf.

4.4.13 When neither the potential participant nor another on his or her behalf can consider the proposal and give consent, an HREC may, having taken account of relevant jurisdictional laws, approve a research project without prior consent if:

a. there is no reason to believe that, were the participant or the participant's representative to be informed of the proposal, he or she would be unwilling to consent;

b. the risks of harm to individuals, families or groups linked to the participant, or to their financial or social interests, are minimised;

c. the project is not controversial and does not involve significant moral or cultural sensitivities in the community; and, where the research is interventional, only if in addition:

d. the research supports a reasonable possibility of benefit over standard care;

e. any risk or burden of the intervention to the participant is justified by its potential benefits to him or her;

f. inclusion in the research project is not contrary to the interests of the participant.

4.4.14 As soon as reasonably possible, the participant and/or the participant's relatives and authorised representative should be informed of the participant's inclusion in the research and of the option to withdraw from it without any reduction in quality of care.

Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness

Introduction

The three kinds of condition discussed in this chapter are different. They are discussed in the one chapter, however, because many of the ethical issues they raise about research participation are very similar.

People with a cognitive impairment, an intellectual disability, or a mental illness are entitled to participate in research. While research involving these people need not be limited to their particular impairment, disability or illness, their distinctive vulnerabilities as research participants should be taken into account.

The capacity of a person with any of these conditions to consent to research, and the ability to participate in it, can vary for many reasons, including:

a. the nature of the condition;

b. the person's medication or treatment;

c. the person's discomfort or distress;

d. the complexity of the research project;

e. fluctuations in the condition. For example, while intellectual disability is usually permanent, cognitive impairment and mental illness are often temporary or episodic.

Even when capable of giving consent and participating, people with these conditions may be more-than-usually vulnerable to various forms of discomfort and stress.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8, except where that research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review.

Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.

Guidelines

Research merit and integrity

4.5.1 The research design should take into account factors that may affect the capacity to receive information, to consent to the research, or to participate in it. These factors may be permanent or may vary over time.

4.5.2 Care should be taken to determine whether participants' cognitive impairment, intellectual disability or mental illness increases their susceptibility to some forms of discomfort or distress. Ways of minimising effects of this susceptibility should be described in the research proposal.

Justice

4.5.3 People with a cognitive impairment, an intellectual disability, or a mental illness are entitled to participate in research, and to do so for altruistic reasons.

Beneficence

4.5.4 Because of the participants' distinctive vulnerability, care should be taken to ensure that the risks and any burden involved in the proposed research are justified by the potential benefits of the research.

Respect

4.5.5 Consent to participation in research by someone with a cognitive impairment, an intellectual disability, or a mental illness should be sought

either from that person if he or she has the capacity to consent, or from the person's guardian or any person or organisation authorised by law.

4.5.6 Where the impairment, disability or illness is temporary or episodic, an attempt should be made to seek consent at a time when the condition does not interfere with the person's capacity to give consent.

4.5.7 The process of seeking the person's consent should include discussion of any possibility that his or her capacity to consent or to participate in the research may vary or be lost altogether. The participant's wishes about what should happen in that circumstance should be followed unless changed circumstances mean that acting in accordance with those wishes would be contrary to the participant's best interests.

4.5.8 Consent under paragraph 4.5.6 should be witnessed by a person who has the capacity to understand the merits, risks and procedures of the research, is independent of the research team and, where possible, knows the participant and is familiar with his or her condition.

4.5.9 Where consent has been given by a person authorised by law, the researcher should nevertheless explain to the participant, as far as possible, what the research is about and what participation involves. Should the participant at any time recover the capacity to consent, the researcher should offer him or her the opportunity to continue participation (under the terms of paragraph 4.5.7) or to withdraw.

4.5.10 Researchers should inform HRECs how they propose to determine the capacity of a person with a cognitive impairment, an intellectual disability, or a mental illness to consent to the research. This information should include:

a. how the decision about the person's capacity will be made;

b. who will make that decision;

c. the criteria that will be used in making the decision; and

d. the process for reviewing, during the research, the participant's capacity to consent and to participate in the research.

4.5.11 Refusal or reluctance to participate in a research project by a person with a cognitive impairment, an intellectual disability, or a mental illness should be respected.

Appendix B

International Covenant on Civil and Political Rights (ICCPR)

The ICCPR sets out a number of civil and political rights to be guaranteed to individuals by parties to the Covenant. Article 7 of the ICCPR provides that "no one shall be subjected without his free consent to medical or scientific experimentation".

The United Nations adopted the ICCPR in 1966, and New Zealand agreed to be bound by the Covenant in 1978.[25] New Zealand subsequently affirmed its commitment to the ICCPR by passing the New Zealand Bill of Rights Act 1990. That Act incorporates many of the rights in the ICCPR, including the right not to be subjected to non-consensual experimentation.

United Nations Convention on the Rights of Persons with Disabilities (UNCRPD)

New Zealand is also a party to the UNCRPD,[26] the purpose of which is to "promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity". The UNCRPD requires parties to prohibit all discrimination on the basis of disability and to guarantee persons with disabilities equal and effective legal protection against discrimination.

Article 12 of the UNCRPD affirms that persons with disabilities have the right to be treated equally before the law and to enjoy legal capacity on an equal basis with others in all aspects of life. In its general comment on Article 12, the United Nations Committee on the Rights of Persons with Disabilities stated:

> [L]legal capacity is the ability to hold rights and duties (legal standing) and to exercise those rights and duties (legal agency). It is the key to accessing meaningful participation in society.

---

[25] *The ICCPR was ratified by New Zealand on 28 December 1978.*

[26] *The UNCRPD was ratified by New Zealand on 9 September 2008.*

To that effect, the Committee has also made it clear that the UNCRPD requires a shift from substituted decision-making (where decisions are made by others on behalf of the relevant individual) to supported decision-making (where the individual receives support that allows him or her to make the decision).[27] This means that, in all circumstances, people with disabilities should be supported to make their own decisions in respect of research, rather than others making decisions for them.

United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)

The UNDRIP establishes a universal framework of minimum standards for the survival, dignity, well-being and rights of indigenous peoples. It also contains provisions that are consistent with the duties and principles inherent in the Treaty of Waitangi, such as partnership and mutual respect. The UNDRIP states, among other things, that indigenous peoples have rights to self-determination and autonomy, and the right to participate in decision-making in matters that would affect their rights.

New Zealand declared its formal support for the UNDRIP in 2010.

Declaration of Helsinki

The Declaration of Helsinki is a policy statement developed by the World Medical Association. It sets out a series of ethical principles regarding medical research on human subjects. The Declaration has been endorsed by various New Zealand bodies, including the New Zealand Medical Association.

The Declaration includes principles to be applied where proposed research involves consumers who are incapable of giving informed consent:

- An individual who is incapable of giving informed consent must not be included in a research study that has no likelihood of benefit for that individual unless:
  - the study is intended to promote the health of the group represented by the potential subject;
  - the research cannot instead be performed with persons capable of providing informed consent; and
  - the research entails only minimal risk and minimal burden.

[27] *Committee on the Rights of Persons with Disabilities General Comment on Article 12: Equal recognition before the law (2014) at [3].*

- Research involving subjects who are physically or mentally incapable of giving consent may only take place if the physical or mental condition that prevents the subjects from giving informed consent is a necessary characteristic of the research group.
- Where a potential research participant is incapable of giving informed consent, the researcher must seek informed consent from a legally authorised representative. If no such representative is available and the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.
- Where a potential research subject who is deemed incapable of giving informed consent is able to give assent[28] to decisions about participation in research, the researcher must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

[28] *Assent refers to an expression of approval or agreement not amounting to informed consent.*

Appendix C: National Ethics Advisory Committee (NEAC) Guidelines New Zealand

NEAC currently has separate guidelines for observational and intervention studies. However, the present guidelines are under review, and it has been proposed that the new guidelines combine the observational and interventional guidelines into one document.

NEAC Ethical Guidelines for Intervention Studies

The NEAC Ethical Guidelines for Intervention Studies allow for interventional research to be done on consumers who cannot consent provided that a number of criteria, in addition to the legal requirements set out above, are met. The guidelines separate the considerations that must be given to "non-consensual studies" and to studies involving "vulnerable people". For the research being considered as part of this consultation, both sets of considerations are likely to be relevant.

- Participants should not be enrolled without consent if they can give consent before the study.
- Where competency is limited, participants should be involved in decision-making as much as possible and are entitled to make informed decisions to the extent appropriate to their level of competence.
- Intervention studies with no therapeutic intent should be undertaken only with the prior informed consent of the competent individual, unless a legal proxy can consent for an incompetent individual.
- If a person is not competent to make an informed decision about participating in a therapeutic study, then the decision may be made by an individual who is legally entitled to decide on behalf of that person. If no such individual is available, and the researcher can legally undertake the study, then study participation must:
  - meet appropriate ethical standards, which include the best intervention standard (the intervention(s) in the study are tested against the best proven intervention(s) available

outside the study) and the equipoise standard (the evidence is 'equally poised' as to the overall balance of risks and benefits of each of the interventions offered in the study, so that it cannot be determined in advance which of the groups in a proposed study will be better off);

- be consistent with the views of other suitable people who are interested in the person's welfare and available to advise on this ; and
- be in accordance with a study protocol approved by an ethics committee.

In addition, the guidelines state the following in relation to research involving "vulnerable people":

- Vulnerable people should have the opportunity to be included in high-quality studies on questions that might affect their health, taking the following into account:
  - The study should ask questions that matter to the participant's community, and the answers should benefit the community.
  - Studies should not be performed with vulnerable groups if they can be adequately performed with other groups.
  - Where a study with a vulnerable group is conducted, it should involve the least vulnerable people in that group.
  - Intervention studies should be conducted only if the risk to vulnerable people is at an acceptable minimum.
  - Study participation should be a matter of free and informed decision-making by study participants wherever possible.
- The interests of vulnerable individuals must be protected, and these individuals must not be exploited for the advancement of knowledge.
- When a vulnerable person is competent to decide on participation in a study, that person's decision should be respected. Even when a vulnerable person is competent to decide her or his own study participation, it is often appropriate to notify and seek advice from a person or persons with knowledge of, or responsibilities for, that vulnerable person.

- Where a study involving vulnerable people is conducted, additional support might need to be provided to ensure that such people can participate fully.
- If the competence of a vulnerable person to decide her or his own study participation is unclear, it may be appropriate for a researcher to seek both the informed consent of that person and the informed agreement of another person who is interested in, or has responsibilities for, that person's welfare.

NEAC Ethical Guidelines for Observational Studies

The NEAC Ethical Guidelines for Observational Studies set out specific criteria that must be met if a consumer has diminished competence to give informed consent.

The Guidelines require that the studies seek to balance the vulnerability that arises from the participants' diminished competence with the injustice that would arise from their exclusion from the benefits of observational studies in these groups. They also require that these participants are included only when the study question can be addressed only with their participation and when consent has been sought from their legal representatives, while also seeking to ascertain the individual's wishes concerning his or her participation and respecting any dissent to participation from the individual.

Appendix D: Key terms and abbreviations used in this paper

Advance directive/advance consent: an oral or written directive by which a consumer makes a choice about a possible future health care procedure that is intended to be effective only when the consumer is not competent. See page 12.

Authorised representative: a person legally authorised to make decisions on behalf of a consumer who is unable to provide informed consent. An authorised representative will be either a welfare guardian or a person holding an activated enduring power of attorney. See pages 13–14.

Benefit: an advantage gained by a consumer as a result of participating in a study. See page 15.

Best equal interests: a test requiring that the consumer would benefit as much from participating in a particular study as from not participating. The test requires the benefits, risks and burdens of participating in the study to be weighed against the benefits, risks and burdens of the consumer's best alternative to participation. See page 32.

Best interests: a test requiring that participation in a particular study is the consumer's best available option. The test requires the benefits, risks and burdens of participating in the study to be weighed against the benefits, risks and burdens of the consumer's best alternative to participation. See pages 14–15.

Burden: a disadvantage, other than risk, suffered by a consumer as a result of participating in a study. For example, the consumer may be required to undergo procedures, testing and monitoring additional to what would be required for standard treatment. See pages 9 and 31-34.

The Code: the Code of Health and Disability Services Consumers' Rights, a regulation that gives legally enforceable rights to all consumers of health and disability services, and places corresponding obligations on providers of those services. See pages ii–iii and 11–14.

Competent consumer/competent person: a person who has the capacity to make an informed choice and provide informed consent to receiving a health or disability service, including the capacity to understand the relevant information and the possible consequences of the decision and the ability to communicate that decision. See page 1.

Consumer: a person in respect of whom any health care procedure (including health research) is carried out, or a person receiving disability services.

Consumer autonomy: the freedom of a consumer to make his or her own decisions, which underlies the requirement of informed consent. See page 8.

Declaration of Helsinki: a policy statement developed by the World Medical Association that sets out a series of ethical principles regarding medical research on human subjects. See Appendix B.

Delayed consent/retrospective consent: refers to a situation in which a health procedure is carried out on an incompetent consumer without consent. When the consumer later regains competence, he or she is asked to retrospectively provide consent to the procedure that has already been carried out. Delayed/retrospective consent is not a legally valid form of informed consent in New Zealand. See page 12.

EPOA: an enduring power of attorney — an authority granted by a consumer to another person (called an attorney) permitting the attorney to make certain decisions on behalf of the consumer if the consumer becomes incompetent. See pages 13–14.

HDEC: a Health and Disability Ethics Committee. HDECs apply ethical guidelines to reach decisions about whether particular studies should be allowed to proceed. See pages 15–16.

Health and disability research: any scientific investigation that aims to generate knowledge about a health or disability issue that can be applied in the future. See page 6.

Informed consent: permission granted by a person with knowledge and understanding of the relevant facts and possible consequences of the decision, for the person to receive health or disability services. See pages 5, 8 and 11–14.

Interventional study: a study in which the researcher intentionally alters the care or services provided to the participants for the purpose of adding to our knowledge of the health effects of the intervention. See page 6–7.

ICCPR: the International Covenant of Civil and Political Rights, an international instrument that sets out a number of civil and political rights to be guaranteed to individuals by parties to the Covenant. See Appendix B.

Lacking capacity: describes a person who is unable to make an informed choice about receiving a particular health or disability service, generally due to either an inability to understand the relevant information or an inability to communicate a decision. Lacking capacity is used interchangeably with the terms “not competent” and “incompetent”. See pages 1 and 5.

Medical experiment: a term used in the Protection of Personal and Property Rights Act 1988. Its meaning has not yet been considered by the New Zealand courts. See pages 13–14. The term “medical and scientific experimentation” is also used in the New Zealand Bill of Rights Act 1990.

NEAC: the National Ethics Advisory Committee, which sets ethical guidelines to be used by researchers and ethics committees. See Appendix C.

Non-therapeutic study: a study in which the intervention being assessed will not provide any direct benefit to the participants. See pages 6–7 and 15.

Not competent/incompetent consumer or person: a person who is unable to make an informed choice about receiving a particular health or disability service, generally due to either an inability to understand the relevant information or an inability to communicate a decision. These terms are used interchangeably with the phrase "lacking capacity". See pages 1 and 5.

Observational study: a study in which the researcher does not control the interventions provided to participants, but simply studies the effects of interventions that would have been provided regardless of participation in the study. See pages 7 and 19–20.

Placebo: a simulated or otherwise medically ineffective treatment, such as a sugar pill. See pages 6 and 15.

Provider: a provider of health services or disability services. See page 6.

PPPRA: the Protection of Personal and Property Rights Act 1988, which provides for the protection and promotion of the personal and property rights of people who are not fully able to manage their own affairs. See page 13.

Risk: exposure of a consumer to a possibility of harm as a result of his or her participation in a study. See page 8.

Therapeutic study: a study in which the intervention being assessed may provide a direct benefit to some or all of the research participants. See page 7.

UNCRPD: the United Nations Convention on the Rights of Persons with Disabilities, the purpose of which is to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity. See page 56.

UNDRIP: the United Nations Declaration on the Rights of Indigenous Peoples, which establishes a universal framework of minimum standards for the survival, dignity, well-being and rights of indigenous peoples. See page 57.

Veto: the right to refuse or reject permission for an incompetent consumer to participate in health and disability research. See page 37.

Welfare guardian: a person appointed by the court to make certain decisions on behalf of someone who is not competent. See pages 13–14.

Disclaimer

All the recommended reading resources, links to organisations and other websites provided in this booklet are for reader reference only and should not be treated as an endorsement by the Health and Disability Commissioner.

HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Health and Disability Commissioner
PO BOX 11934, Wellington 6142

Free phone: 0800 11 22 33
Fax: 04 494 7901
Email: hdc@hdc.org.nz
Website: www.hdc.org.nz