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

OFFICE OF THE HEALTH AND DISABILITY COMMISSIONER

Health & Disability Commissioner
Te Toihau Hauora, Hauātanga

Executive summary

Introduction

This review by the Health and Disability Commissioner examines whether changes are needed to the current rules relating to health and disability research involving adults[1] who are unable to give informed consent[2] to participate in research.

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

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

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

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

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

Overall, the review has addressed three key questions:

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

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

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

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

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

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

A comprehensive set of principles

The Code is only one part of an overall system, with other legal and ethical parameters contained in the New Zealand Bill of Rights Act (1990) (NZBORA), the Protection of Personal Property and Rights Act 1988 (PPPR Act), National Ethics Advisory Committee (NEAC) guidelines, Health and Disability Ethics Committees' (HDECs) Standard Operating Procedures (SOPs), and the United Nations Convention on the Rights of People with Disabilities. There is a need to ensure that different parts of the system work well together, but the first step is to agree on what a comprehensive set of principles ought to be. The principles proposed below relate to study approval and the enrolment of individuals in an approved study. They are intended to ensure that research with adults unable to consent occurs only if there is no other way to answer the research question, that it is directly relevant to the participants' condition, that it is valuable and likely to advance knowledge, and that individuals are protected from no more than minimal foreseeable risk of harm and no more than minimal foreseeable burden.

No changes are proposed at this time regarding who makes the decision to enrol an individual. The current rules would continue to apply, namely, that a person legally entitled to consent on behalf of the consumer[3] would give consent where possible, and otherwise the provider would make the decision (as per Right 7(4) of the Code). Additional safeguards are proposed, however, including the right of "other suitable persons" to veto participation in the research. Of particular concern are consumers who have no person legally entitled to consent on their behalf and no suitable person who could be consulted, for example, a person with severe dementia in an aged residential care facility who has not appointed an enduring power of attorney (EPOA), the Family Court has not appointed a welfare guardian, and the person has no family or friends interested in his or her welfare. These people may be isolated and are extremely vulnerable, and should never be enrolled in research.

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

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

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

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

7c	If suitable persons cannot be consulted, then: • In situations where there is no time to consult with suitable persons, enrolment can proceed (as long as other provisions are met), with a requirement that consultation occur as soon as possible with those persons having the option to veto participation (withdraw if practicable and/or prohibit use of data) at that time, and • In situations where the proposed participant has no suitable persons who could be consulted, that person must not be enrolled in the research study	Study approval AND Individual enrolment
8	The participant's wishes must be taken into account to the extent possible: • Efforts must be made to obtain prior consent or assent • Any known prior objection must be respected • Any indication of dissent must be respected and responded to on an individual basis • If there is reason to believe that participation would be consistent with the person's wishes, that must be complied with	Individual enrolment
9	If the person regains capacity to consent, or regains some competence to be supported in a decision, where practicable, the person must be given the opportunity to consent or refuse consent to continued participation in the research and/or for the use of any data already collected	Individual enrolment

Ethics review and approval processes and governance

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

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

Monitoring and evaluation of any changes

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

Recommendations

It is recommended that the Minister of Health:

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

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

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

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

   a. A comprehensive set of principles with an appropriate regulatory framework to underpin the legal and ethical settings for health and disability research involving adults unable to consent (see Recommendation 5);

   b. A specialised ethics review and approval process and enhanced governance system in relation to health and disability research involving adults unable to consent (see Recommendation 6);

   c. Monitoring and evaluation of any changes to the legal and ethical framework, systems, and processes relating to health and disability research with adults unable to consent, with a particular focus on outcomes for participants.

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

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

a. Such research should be permitted only when the research question cannot be answered without involving adults unable to consent;

b. Such research should be permitted only when the purpose of the research is to advance knowledge about the condition causing the participants' impairment or its treatment or relevant services;

c. Such research should be scientifically robust, worthwhile (have social value), and aim to answer a genuine research question;

d. Such research should involve no more than minimal foreseeable risk and no more than minimal foreseeable burden to participants;

e. Where the provider is the decision-maker with regard to enrolment of participants, the management of any perceived or actual conflicts of interest arising from the researcher and the provider being the same person or closely aligned should be actively addressed in research protocols to the satisfaction of the ethics committee.

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

a. That no health and disability research with adult participants who are unable to consent should take place unless the research has received the approval of an ethics committee;

b. Amending pathways to enable all health and disability research studies involving adults unable to consent to be considered by an ethics committee;

c. Clear guidance being developed about defining and assessing minimal foreseeable risk and minimal foreseeable burden;

d. A specialist ethics committee being established with responsibility for reviewing all health and disability research involving adults unable to consent that would:

   i. Have the necessary expertise to evaluate risks and other considerations, and/or have the resources to commission its own peer review and risk assessment;

   ii. Be resourced to oversee auditing and follow-up of approved research studies;

   iii. Play a role in monitoring and oversight of approved research studies and the outcomes for participants.

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

a. A consumer who is unable to give informed consent may only be enrolled in health and disability research that has been approved by an ethics committee;

b. A consumer who is unable to give informed consent may be enrolled in health and disability research only if the research will involve no more than minimal foreseeable risk and no more than minimal foreseeable burden to that consumer;

c. The consumer's known wishes should be taken into account as practicable;

d. Any indications of dissent by the consumer should be respected and responded to on an individual basis;

e. If the research participant regains capacity to consent, or some capacity to be supported in a decision, where practicable that consumer must, as soon as possible, be given the opportunity to give or decline informed consent to continued participation in the research, and/or to the use of data about that consumer that has already been collected;

f. The decision about enrolling such a consumer in an approved research study should be made by a person legally entitled to consent on behalf of the consumer, where possible;

g. Where there is no person legally entitled to consent on behalf of the consumer, the decision-maker about enrolling an individual should be the provider;

h. Where the provider is the decision-maker:

   i. Available suitable persons interested in the consumer's welfare must be consulted (as now required under Right 7(4)), and those suitable persons should have the right to veto participation in the research at any time for any reason;

   ii. If the consumer has no suitable person interested in his or her welfare to consult, he or she should not be enrolled in research;

   iii. If because of the nature of the research, there is no time to identify whether there are suitable persons who could be consulted or to consult them, the consumer may be enrolled in the research, but suitable persons must be consulted as soon as possible and have the right to veto further participation and to withdraw the data collected if practicable.

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

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

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

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