HDC Consultation

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

Consultation response form

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

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

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

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

To provide us with your comments, either:

a) complete the form online; or

b) print the form, record your answers on the form and return it to PO Box 11934, Wellington 6142. Add additional pages if you wish to do so.

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

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

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

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

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

Case Study E questions

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

Yes/No/Unsure

E.2
Please 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.

Consultation questions

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?

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

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

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

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

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

Yes/No/Unsure

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

Dissent

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

Consultation Question 2

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

Yes /No/Unsure

2.2 Please give reasons for your answer.

Delayed consent

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

Consultation Question 3

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.

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.

Consultation Question 4

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

Yes/No/Unsure

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

Interests of others to be taken into account

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

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

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

Consultation Question 5

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

Yes/No/Unsure

5.2 Please give reasons for your answer.

If the answer to question 5.1 is yes:

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

Yes/No/Unsure

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

1.

2.

3.

4.

5.

Any others?

Ethics committee approval

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

Consultation Question 6

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

Yes/No/Unsure

6.2 Please give reasons for your answer.

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

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.

Who decides?

Consultation Question 8

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 (see, e.g., Case Study D)? 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.

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

Thank you for your contribution to this consultation.

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

Please state your

Name:

Organisation:

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982. If you consider that all or part of your submission should be treated as confidential, please state this clearly when making your submission and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information. Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.