

# Confidential Submissions

## National Ethics Advisory Committee

### Introduction

This document outlines the submissions made to the National Ethics Advisory Committee Public Consultation on the *draft National Ethics Standards for Health and Disability Research*.

The consultation received 103 submissions in total. This document **does not** contain submissions that are **not** approved for publication.

### Caveats

- Submissions are not edited in order to preserve their original state.
- Cases where a likert scale response states 'Strongly' is 'Strongly Agree'. This is an IT issue caused by an error in the online consultation. The error has been amended for the data tables generated from these responses.
- Please note that 30 submissions were submissions received in PDF or paper form, including scanned letters. All efforts have been made to enhance readability.

Response number	1
Name	[redacted]
Organisation	[redacted]
Role	Professor , teacher , researcher
Interest group	Academic
Publish response	Yes

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Disagree

#### Please outline your reasons:

It is very complicated and unnecessarily detailed. There needs to be a short version

The standards are applicable to all types of health and disability research  
Strongly Disagree

#### Please outline your reasons:

The problem is they cover too much. I just want to do simple behavioural interventions and I have to answer questions about drugs and blood sample which are totally irrelevant

The standards balance protecting individuals with the realities of conducting research  
Strongly Disagree

#### Please outline your reasons:

The HDEC committees get in to research design. I had to do 4 resubmits on one study and they wanted an external referee and were not happy with that one and asked for another. The first one has just become a professor of nursing and epidemiology. They need to stick to protecting patients

The standards support researchers to navigate ethical challenges in health research  
Neutral

#### Please outline your reasons:

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:**  
Disagree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Disagree

**Standards - reflect the principles of the Treaty of Waitangi:**  
Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Strongly Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:** Neutral

**Standards - protect and reassure the community:**

Neutral

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Neutral

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Neutral

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. : I am confused by this question**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Disagree

**Please outline any missing ethical issues or principles:** It does this but this makes it too unwieldy

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Strongly Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

The issue is that the patient information sheet is way too complicated. Virtually no participant reads it. They are happy with a verbal discussion with the interviewer. A brief summary would be much more workable.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If yes, please provide feedback**

Yes

**Please provide feedback with reference to the paragraph(s) in question:** see above

### **Research with participants who are unable to consent**

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

NA

### **Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

Deception is a poor word. There is the concept of resentful demoralization where the control group know they are getting an control intervention. For subjective outcomes like pain or mood/anxiety

this affects the validity of the study. It is important that participants do not know what they are not getting otherwise the study is ruined.

### **Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

The design issues should not be a matter for the ethics committee unless they think it impinges on the safety of participants. They should rely on the referees.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

Covers too many studies e.g. dangerous new drugs versus simple behavioural interventions

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Charging participants**

**Please outline your reasons:**

The other issue is paying participants. some committees don't allow this to be mentioned in the information sheet. When I have offered a payment afterwards many participants say that I should have mentioned that at the beginning they may have been keener to do the study.

### **Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Big data and new ways of using data

Neutral

**Please provide feedback:**

### **Databanks**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Human tissue**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:** Keep tissue section as a different application as it is way more complicated

### **Biobanks**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**



The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research with stem cells**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

<b>Response number</b>	<b>2</b>
Name	[redacted]
Organisation	[redacted]
Role	Bioinformatics Research Analyst
Interest group	Academic
Publish response	Yes

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Strongly Agree

#### Please outline your reasons:

The standards are [in general] suitably prescriptive and cover most of what I think is an ethical concern in research.

The standards are applicable to all types of health and disability research  
Neutral

#### Please outline your reasons:

I don't have enough domain knowledge to know if it's applicable to areas outside my own interests.

The standards balance protecting individuals with the realities of conducting research  
Disagree

#### Please outline your reasons:

Individual protection needs more emphasis; I don't think it's appropriate to justify individual disrespect using the shield of "standard research practise".

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

The principles, in particular, provide a good grounding. It would be a great idea to relate at least major sections back to the dominant principles to keep reminding people that the ethical guidelines are attached to the skeleton of the principles.

### Overall do the Standards?

#### Standards - safeguard the rights and interests of participants in research:

Agree

#### Standards - promote high-quality ethical research for social, cultural and economic wellbeing:

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Strongly Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Strongly Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:** Neutral

**Standards - protect and reassure the community:**

Disagree

### Coverage of ethical guidance

The standards adequately cover the ethical challenges that are present in health and disability research

Disagree

**Please describe the ethical challenges that are missing:**

Personal research. If I'm studying myself (i.e. I serve a dual-role as both participant and researcher), what do I need to do to demonstrate informed consent? Who else needs to be consulted? Do I need ethics approval for publishing results of such a study?

### Merging the observational and interventional guidelines

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

The difference between the types is stated, although I don't recall much emphasis on how points differ in their interpretation when applied to observational or interventional research.

### Scope of the standards and non-research activities

**Is the scope of the document clear?**

Neutral

**Please outline your reasons or suggested improvements:**

The scope feels like an uncomfortable merging of different concepts:

- \* Generation of knowledge
- \* Having a purpose
- \* Collecting data
- \* Analysing data
- \* Interactions with participants

It seems like the definition is trying to skirt around some non-definitions. There are a lot of conditional statements. The "what is not research" section helps to clarify this a little bit, but mostly through examples, without any overarching non-research definition.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

S4.6 Is self-research (where the researcher and participant are the same person) within the scope of the standards?

S4.6 I don't understand why surveillance is not considered research. I don't think it's appropriate to state that something is not research because it is not obviously generalisable. Perhaps the distinction would be better stated as "basic research" vs "applied research". See Wikipedia [<https://en.wikipedia.org/wiki/Research>] for more information. Any surveillance or continual monitoring \*should\* require proper process and ethical approval. Yes, I understand that will cause an uproar in many businesses.

S4.7-4.22 The "Innovative practise" definition and explanation is great. More like this, please. Otherwise, things are very unbalanced; it makes it seem like innovative practise is the only form of research that matters.

## **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Great section; a core set of ethical principles is very useful for framing the remainder of the document.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Communication is a very important part of research. I think that researchers should have a specified means of communication directly to the \*participants\*, rather than just the community that they are members of.

When someone involved in research stops communicating with others, that's really bad. I've had a response along the lines of, "I don't want to discuss this further with you" on multiple occasions, including from the appointed academic mediator, and the Ethics Committees manager. There's no appropriate (or prescribed) way to advance research in such a situation, which means that the most ethically-appropriate action is to withdraw ethical approval and halt the research immediately. This leaves behind a lot of wasted time and money, but more is wasted by trying to continue in such a situation.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Generally, the principles are great. My main comments are around needing more emphasis on participant control - making that implicit principle explicit. "Researchers are expected to learn as well as gather data in research, to collaborate and to give back to the community (eg, through koha and sharing ideas)." [S

5.7] - a good principle to have; I think a minimal sharing protocol needs to be specified in ethics applications. But I also think it needs to go a bit further than this:

researchers should have a specified means of communication directly to the \*participants\*, rather than just the community that they are members of.

Also S 5.7: "The relationship between researchers and participants (and New Zealand communities) must involve trust, respect and integrity." Definitely.

\*Informed\* control, and \*informed\* trust, is important in research.

Although in S 5.7, the "Tika" and "Mana" sections do not have a prescriptive final sentence, as in other sections: "Researchers must / are expected to...." Adding such a sentence would do well to clarify the meaning of the terms.

S 5.8: "An important mechanism for respecting participants' autonomy in research is for researchers to seek their free, informed and ongoing consent." -- Yes.

Approval is a continual process, and can be revoked by participants at any time. Researchers need to be aware of this.

## **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

This section is great, in that it demonstrates (in a prescriptive fashion) ways in which research can be made more equitable.

As pointed out in 6.11, "All research in New Zealand is of interest to Māori: every study can offer a training opportunity for a Māori researcher; every study may carry risks or produce benefits for Māori; and all research has the potential to help Māori achieve their aspirations. Every study in New Zealand therefore should consider the degree to which it can contribute to Māori health outcomes."

This section is really about making research more fair, and more generally applicable. It may be necessary to single out Māori as a disadvantaged group, but it's important for researchers to think about all biases or prejudices that they may have. By excluding Māori from research (both as participants and as researchers), the researchers are doing a disservice to the scientific community as a whole.

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

It's impossible to cover everything. My suggestion (especially for this section) would be to link sections back to the Te Ara Tika principles, pointing out that these are guidelines that are derived from the application of those principles to research.

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Disagree

**Please provide feedback with reference to the paragraph(s) in question. :**

"As above" is not useful, and potentially harmful. Consider what that statement means for "Māori centred research":

- \* it implies that there is a need for and institutional review that confirms the exclusion of Māori is valid and justified [contradictory].
- \* it implies that the default control for the path of research lies with the [western] institution

Further, the least explanation is devoted to "Research not involving Māori". There needs to be an expansion of that, pointing out why it's a problem. I also think that there should be an independent [ideally Māori-led] "review that confirms that exclusion of Māori is valid and justified". If an institution has only ever done research that excludes Māori, it would be silly to expect them to not be able to find some random justification for continuing along that path.

**Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

This should really be a subsection of the previous section. It also typecasts non-Māori and non-Pacific individuals as not being interested in these qualities, whereas what is frequently found is that improving research for under-represented minorities also improves research for other groups as well.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

This repeats a lot of what was in the previous section. It would be better to separate out those repetitive bits as a separate section, and only detail the things that are different for the Pacific people. As stated elsewhere in the consultation document, "overburdening participants with information that reduces their ability to provide effective informed consent." This applies to guidelines as well; too much information (particularly when repeated) can be harmful in getting people to understand something.

Here's a rough-cut example of generalisations that take the common elements from this section:

Any ethnic term, such as 'Pacific peoples', does not refer to one homogeneous group of people. People come from a distinctive range of cultures, heritages, languages and diverse communities. The diversity can be both ethnic and national and includes people born all over the world, as well as those who are born in New Zealand.

Communities can have a holistic perspective of health and wellbeing. This includes an interconnectedness between beliefs and values, as well as between cultural, emotional and social dimensions, and a view that health and wellbeing are often influenced by family and community, specifically in relation to health and illness.

A research protocol must demonstrate cultural integrity and should be developed only after the researchers have established meaningful relationships with the ethnic communities involved.

Research protocols must describe how the study will address the inequities in health outcomes of under-represented minorities.

Researchers should aim to understand individual and community dimensions of health as well as the basis on which participant engagement in research is founded.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

The title of this section is incorrect, and that colours my interpretation of the section. It should instead be titled as in the first subsection (i.e. "Vulnerable participants"). The additional "colour" paragraphs prior to that are better placed within the "Vulnerable participants" section.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

This statement, "The section covers all relevant ethical issues and or principles for health and disability research in New Zealand", is not appropriate (for this section, and for other sections). At best, the entirety of the consultation document "covers all relevant ethical issues and or principles for health and disability research in New Zealand"; any particular section is not sufficient.

If this section were really about participant categories, then it should also include an "other participant" section, or similar.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

Informed, non-coerced consent is a tricky ideal, made even more tricky by allowing research where such consent is not provided. I don't think that "the ends justify the means": research done badly to achieve a good goal is still research done badly.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

See above.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

I disagree with S 9.22:

"If they do not significantly amend the study, researchers should consider participants' consent to be ongoing unless they have reason to believe a participant is withdrawing consent."

I think the researchers actively need to maintain consent, especially where public disclosure is involved (in any form). Public disclosure must be authorised by participants. Agreements made for blanket approval of public disclosure (e.g. 'there is no need to approve every student presentation') should not be allowed.

One of the issues with the research that I did was that the participant's representatives didn't feel they were sufficiently informed about dissemination of research, even though that was authorised in the initial agreement, and even though I was persistently trying (to the degree of annoying the participant representatives) to inform the participants about my research.

--

9.31: "not overburdening participants with information that reduces their ability to provide effective informed consent"

vs 9.32: "the higher the risks participants face... the more detailed the information"

That should be, "the higher the risks, the more clarity required"

--



S 9.37/9.38: I will reiterate my distrust of biobanking; it removes control from participants to satisfy the demands of centralised management and academic efficiency. This is not, "You participate in this research", it's, "Here's what we're doing; if you don't like it, that's your problem". Here are a few phrases from these subsections that concern me:

- \* "good governance structures" [removing control]
- \* "state... whether there is a cultural protocol for its disposal" [statement; no participant choice]
- \* "when a tissue sample is sent overseas... without New Zealand representation" [removing control]
- \* "whether the donor's identity and details will remain linked with the sample" [statement; no participant choice]
- \* "whether the donor can withdraw consent" [consent should \*always\* be able to be withdrawn]
- \* "they relinquish their right to withdraw consent" [... it's not a right, then. But it should be]
- \* "whether the donor may be contacted in the future about their tissue sample" [statement; no participant choice]
- \* "acknowledge that the donor will not own any intellectual property that may arise from any future research" [this is worse than a statement of a "whether"; this is encouraging researchers to be non-participatory]

### Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

"the law on research with participants who are unable to consent restricts when research can be carried out in this population."

Good. If informed consent is not possible from a participant, or their appointed representative, then research, or surveillance, or whatever else you want to call it, shouldn't be carried out.

"Once researchers have demonstrated that the participation of individuals who are unable to consent are necessary to answer the research question"

If informed, uncoerced consent can be obtained after the data is acquired, but before the results are analysed, then I would consider that acceptable [consent is a continual process]. Otherwise, the researchers should be asking a different question.

Attempting to take this to the extreme, "What happens to brain activity when I drive a hot stake through the heart of an unconscious crash victim who will die in 10 minutes?" is not something that can be consented to in an informed fashion, either prior to the research, or after the research is carried out. It's also not a question that should be answered through research.

### Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

I don't think that "the ends justify the means": research done badly to achieve a good goal is still research done badly.

If informed, uncoerced consent can be obtained after the data is acquired, but before the results are analysed, then I would consider that acceptable [consent is a continual process]. Otherwise, the researchers should be asking a different question.

### Research benefits and harms

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

This seems to be a good summary of potential harms; it made me think about the actions of research in terms of harms as well as benefits.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

At this point I'm starting to write more fluff, because there are too many questions, and their structure is too similar.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

This section has been linked back to Te Ara Tika, setting a good foundation for the guidelines.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

S. 11.10-11.11 "Protocol" has a different meaning in my area(s) of medical research. I would use "Proposal" instead of "Protocol". A research protocol tells someone how they can carry out a specific task, and doesn't [typically] have these things:

Study site, sponsor

Literature review\* study justification

... actually, pretty much everything there. This is a "Research proposal", not a "Research protocol". See 11.23, where "research proposal" is used.

### Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

I liked the verbosity of this section. It made me aware of a couple of study designed that I hadn't previously considered or thought about (in particular, Equipoise, and that control groups should receive established effective interventions).

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

It's great to see another linking to one of the principles (whakapapa), and acknowledging that research practises have their own whakapapa (which in most cases are hidden from people evaluating the ethics of research).

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Open, transparent research should be highlighted here.

While it's not appropriate to make individual-level data available to others in an uncontrolled setting (and possibly not even in a research setting), publicly reporting research proposals and results (even if they are null results) can substantially reduce harm in the future.

Researchers should publish (where possible) in open-access journals, especially if their research was funded by a public grant; funds should be set aside in the grant for this to be carried out.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

S 13, Standards. I would also add:

\* Full research results must be made available to all participants at no cost

Of course, the easiest and cheapest way to do this (in most cases) would be to make the results available to \*everyone\* at no cost.

--

3.44 "dual-role researchers can face several significant ethical challenges.... Some options for managing these issues are... recognising the conflict and declaring it, and mitigating risks to informed consent" I like that this is explicit; it's a good way to do research.

### Charging participants

#### **Please outline your reasons:**

I don't think people should be paying to participate in research; the onus should be on the researchers to find funds for that research. Research is likely to get cheaper in the future, particularly if genetics is involved.

Related, I think that 23andMe selling their participant data (acquired from paying customers) to drug companies is wrong, and don't want to see anything remotely like that in New Zealand.

### Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

#### **Please outline your reasons why the section is or is not fit for purpose:**

I like the verbosity here, and that it links back to the principle of taonga (S 14.4).

However, it was distracting to start off with a meaningless (and incorrect) cycle diagram. A few examples:

- \* I don't think that research data should stay around in perpetuity.
- \* I don't think management should happen \*after\* data creation and deposition.
- \* If data is continually used and updated, there should be a database, and the archived data shouldn't be re-used.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

#### **Please outline any missing ethical issues or principles:**

This is missing the ethical issues associated with Innovative Practise, Research involving Māori, Informed consent, and a few others.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

#### **Please provide feedback with reference to the paragraph(s) in question:** finger-slip typo:

14.37 "5esearchers should establish"

S14.49: When research involves the special features identified above, researchers should carefully consider whether they should undertake robust, active and ongoing engagement with relevant

communities and stakeholders to establish whether the proposed data use is acceptable."

■■[great]

Aside: engagement and communication of this nature requires active communication from both sides. Silence and stonewalling by the communities and stakeholders prevents this, is an indication that consent should be re-evaluated, and may suggest the project should be stopped.

14.56 "Obtaining informed consent to link data must always be the default starting point... researchers may link data only if an ethics committee is satisfied that they meet the conditions for waiver of consent." -- See Dropbox's issue, where informed consent was not provided from researchers [<https://twitter.com/cfiesler/status/1022103087098388480>]

## Big data and new ways of using data

Neutral

### **Please provide feedback:**

The "Interpretation harms" could be expanded upon.

We need to be more aware of the harm that computer programs can cause; they are not neutral things. Algorithms (including those that encode artificial intelligence and/or machine learning) carry the biases of their programmers.

Any application of computer algorithms to a particular task (including AI, whatever that means) needs to consider bias. Algorithms are imbued with the mauri and tikanga (or wairua?) of their programmers; when created without thought, they're more likely to amplify inequities than correct them.

Programmers create algorithms that share some of the qualities of their creator. The algorithm's eyes cannot be any better than those of the programmers; if a programmer is blind to something, the algorithm will be as well.

AI is usually based around an attempt to get an algorithm to learn from its experiences, but that learning is heavily dependent on the senses and filters provided to it by the programmers.

If care is not taken in creating an algorithm; if it is created without enough life to properly learn from or process its environment, then it can steal life. There's a great passage in *Going Postal* about that:

"Do you understand what I'm saying?" shouted Moist. "You can't just go around killing people!"

"Why Not? You Do." The golem lowered his arm.

"What?" snapped Moist. "I do not! Who told you that?"

"I Worked It Out. You Have Killed Two Point Three Three Eight People," said the golem calmly.

"I have never laid a finger on anyone in my life, Mr Pump. I may be— all the things you know I am, but I am not a killer! I have never so much as drawn a sword!"

"No, You Have Not. But You Have Stolen, Embezzled, Defrauded And Swindled Without Discrimination, Mr Lipvig. You Have Ruined Businesses And Destroyed

Jobs. When Banks Fail, It Is Seldom Bankers Who Starve. Your Actions Have Taken Money From Those Who Had Little Enough To Begin With. In A Myriad Small Ways You Have Hastened The Deaths Of Many. You Do Not Know Them. You Did Not See Them Bleed. But You Snatched Bread From Their Mouths And Tore Clothes From Their Backs. For Sport, Mr Lipvig. For Sport. For The Joy Of The Game.”

## Databanks

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

### Please outline your reasons why the section is or is not fit for purpose:

It's surprising contrasting this with the previous points about biobanking; they seem to give more respect (and in some cases control) to the participants.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

### Please outline any missing ethical issues or principles:

See Above.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

### Please provide feedback with reference to the paragraph(s) in question:

I think the severity of the incident in 14.61 is understated. This is really bad; research should not be done in such a situation:

"When planning to contact people because their data is included in a databank, the researcher must bear in mind that some people may be unaware that their data was submitted to a databank or may be unfamiliar with the process by which researchers gain access to the data."

## Human tissue

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly

### Please outline your reasons why the section is or is not fit for purpose:

It's great that this acknowledges previous principles.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

### Please outline any missing ethical issues or principles:

Odd statement.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Re: 15.28

Should I consult with my immediate family before I sequence my own DNA and release it publicly?  
Do I need to get approval from my iwi to do that, given that I contain a bit of Māori ancestral DNA?

### **Biobanks**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

This seems to have been written by a different group of people from section 9.38; it's much clearer and gives a lot more control/consent/respect to participants.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

16.2: "need tissue and data to remain potentially re-identifiable, even if they are coded, because tissue and associated data may need to be linked to other sources of health information for studies in the future or to follow up information added over time"

This "potentially re-identifiable" need is also important for the withdrawal of consent (which should \*always\* be possible).

However, I don't like the idea of biobanking. The aggregation of samples or data for academic efficiency, including separate management of sample and results control (e.g. biobanking), removes control from the participants and should not be recommended for a research project. With this viewpoint I accept that I am at odds with a lot of other researchers; centralisation (rather than decentralisation) rules the roost of research right now.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

16.3-16.10; add:

\* If the management structure of the biobank is changed (including company takeover), any existing consent should be considered void, and new informed consent should be obtained for samples. If this is not possible, the samples should be destroyed, with raw data and any associated aggregate results modified to exclude the non-consented samples.

16.12: tissue should never be made non-identifiable. In any case, it's essentially impossible to do that due to the personally-identifiable nature of DNA sequencing.

16.32: the conditions should be at least summarised here. This should \*at least\* require informed consent from the participant, or their personally-appointed representative.

## Research with stem cells

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Good to see this linking back to the principles in 17.18 (although a bit more explanation would be helpful).

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

17.22 "it is yet not permitted" -> "it is not yet permitted"

17.29 I like the "license" idea. It'd be great if this could be expanded more generally to genetic manipulation of cells, and fitting in with [my understanding of] NZ's gun control laws, i.e. license the operator / researcher, rather than the study / cell line. I believe that licensed scientists (at an appropriate level) should be able to manipulate cells beyond 14 days, particularly when the manipulation preserves the natural structure of DNA (e.g. deleting a deleterious genetic variant, or modifying it to match a wildtype variant).

Despite that, it's important to record the whakapapa of cells: any stem cells or cell lines should have tracked metadata / history.

## Compensation for commercially sponsored intervention studies

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

I like this section; it's [comparatively] short, and gets to the point quickly: if there is commercial interest in research, those interests need to pay for the problems they cause.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**



<b>Response number</b>	<b>3</b>
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher
Publish response	Yes

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Strongly Agree

**Please outline your reasons:** Helpful clear guidelines

The standards are applicable to all types of health and disability research  
Strongly Agree

**Please outline your reasons:**

The standards balance protecting individuals with the realities of conducting research  
Strongly Agree

**Please outline your reasons:**

The areas where there are possible vulnerable groups such as children, disabled, emergency are well covered

The standards support researchers to navigate ethical challenges in health research  
Neutral

**Please outline your reasons:**

The ethical challenges are outlined - but it is not totally clear how to address them. We also think that some cross referencing within the document is needed -  
e.g. 4.14 should mention the independent data safety monitoring board which is not discussed until far later in the document at 13.48. Similarly age is mentioned as a possible vulnerable group (not specifying young or old initially ) then later there is a section on research in children and again these should be linked.

Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Strongly Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Strongly Agree

**Standards - reflect the principles of the Treaty of Waitangi:**  
Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Strongly Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Strongly Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Strongly Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

As mentioned previously there are some areas that could be more explicit in how to tackle the challenges.

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Neutral

**Please outline your reasons or suggested improvements:**

We understand the necessity for balancing the need for good ethical consideration with overwork for the committees. We agree that taking audits out of this process is appropriate - especially as this is good practice. However automatic acceptance that masters studies for example dont need ethics is more risky especially as these tend to be more junior research (albeit with supervision) . Further more, this document is not just for HDEC - it needs to be explicit that it is providing governance for all ethics committees (Universities, DHBs).

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

4.1 This paragraph is weak and yet is important to set the scene of the document.

Something much stronger "These standards are applicable to all research under taken in NZ.

4.2 Starting off by saying it is difficult to define research also doesn't engender confidence in the document.

There is also inconsistent formatting in the box under 4.6.

4.7 should be sub-labelled definition.

Throughout the document not all 'Maori' have the macron above it.

4.21 Suggest the innovator is not the best person to get consent but later that the principal investigator is the best person to get consent - is this clear?

## **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

### **Please outline your reasons why the section is or is not fit for purpose:**

Check 5.8 matches the order given in the Figure 1.

Also - non-maleficence - is a term old-fashioned and rarely used (barely heard of by ourselves even as experienced researchers) surely there is a better word for this?

In table 5.8 the 'non-maleficence' suggests "The risks of harm in research should not be greater than its expected benefits". This seems on an extreme level, when for most the risks should be minimal.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

### **Please outline any missing ethical issues or principles:**

The principles are well covered.

### **Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:** See above

## **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

### **Please outline your reasons why the section is or is not fit for purpose:**

Defining 'inequalities' and 'inequities' at beginning would bring clarity to the subsequent paragraphs. It otherwise is a bit laboured to read. Also check the consistency of these words throughout the document.

Also this is the most important section to have the word 'Maori' correctly presented.

Consistency of bullet points.

6.22 - suggest ..." researcher should review previous statistics (incidence and prevalence) of the disorder ...

6.22 - ..."how they will personally benefit.." ?researchers, ?participants

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Here and in other sections - there is mention regarding giving the information back to communities, especially those that have been involved in the research. No-where is the word 'translation' mentioned. This should have a separate section , as well as being referred to throughout the document. 'Informing' is just giving the information - 'translation' is putting findings into context and in the format that can be understood by the community. It is a vital part of making research useful and applicable.

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

### Research involving Pacific peoples

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

See 7.12 - "researchers are also encouraged to involve a Pacific researcher.." seems weak - surely 'strongly encouraged'

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

Here and in other sections - there is mention regarding giving the information back to communities, especially those that have been involved in the research. No-where is the word 'translation' mentioned. This should have a separate section , as well as being referred to throughout the document. 'Informing' is just giving the information - 'translation' is putting findings into context and in the format that can be understood by the community. It is a vital part of making research useful and applicable. (as mentioned previously)

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:** As above

### Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The categories are well outlined.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

8.12 - the bullet point beginning 'vulnerability' should cross reference age to the section on children (e.g. 8.26),

8.25 - suggest that as well - the option of having a nominated independent person outside of the research under question for the participants to talk to if any concern should also be mentioned. Something that the HDEC committees have suggested in the past.

8.36 - regards confidentiality - if children especially youth participating then there also needs to be confidentiality maintained between research and child if revealing something they do not want parents to know.

**Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

9.2 - suggest there should be a reference to 9.18 where there is '(usually in writing)'

9.8 - while we agree with the listing as to what is good to have on an information sheet - there is a balance between putting everything in and making it unreadable

Similarly - 9.34 would make an exhaustive document to read pre-consent - and is in contrast with the recommendation in 9.31. This is also important when measuring the 'Fleisch-Kincaid' reading easeability score.

9.26 - last line delete 'being'. Generally this is a logical idea. Suggest to add 'however participants must be aware at the beginning of the research that ongoing consent will be requested.'

9.41 Modifying the consent process - suggest "Any changes must be sent to the ethics committee for documentation and approval.

9.57 suggest adding 'below' between '....section on..'

9.77 delete 'including'

9.78

### Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft**

**standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes: Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

9.43 - while this is often agreed to at the beginning by researcher - it would be a interesting audit to determine how often it is truly done at the end.

### Research benefits and harms

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Suggest needs an additional '10.26 To protect study participants a Data Monitoring Committee (DMC) should be in place (see 13.48).

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Suggest add a bullet point after 10th bullet point 'Identify who will recruit the participants to ensure impartiality'

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:** Really well outlined

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

12.5 Also if the intervention (e.g. drug) is not going to be available to participants once the study is completed - this must be highlighted to them ahead of time.

12.6 Difficult to understand as it is written - should be offering controls 'standard care' .

12.18 - Should refer to Data Safety Monitoring Committee.

12.24 First bullet point - why would you do a study if you don't expect a benefit?

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

13.19 - last bullet point - when would this ever be used? Is it at all ethical?

Charging participants

**Please outline your reasons:**

When would this ever be used? Is it at all ethical? And who is the arbiter of the importance of one individual/groups' research?

**Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

14.35 - use of these new terms is very helpful

14.50 - need to reference the section number 14.55 need to reference the section number

Big data and new ways of using data

Not Answered

**Please provide feedback:**

**Human tissue**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**



Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

15.39 - bullet point 4 - if using your own updated terminology - need to include 're-identifiable'

15.41 - last bullet point - need to reference the section

### **Research with stem cells**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

17.3 Suggested change "when considering research projects ...with human embryonic stem cells... researchers must.."

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

18.9 - Suggest "may require ongoing, long term..."

18.11 - Suggest you add "and contact details' i.e. not just the name of the contact person.

### **Commercially sensitive information**

This submission does not contain commercially sensitive information

**If your submission contains commercially sensitive information, please let us know where:**

<b>Response number</b>	<b>4</b>
Name	[redacted]
Organisation	[redacted]
Role	Research Manager
Interest group	Clinical team
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

I think that the draft covers the key issues but is quite complex to follow. It is very narrative.

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

I think this document sets a good balance - and that ethics committees are able to interpret this to enact a more sensible approach to review going forward.

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:** Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

Is the scope of the document clear?

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

As stated in overall statement, the guideline is very wordy and that is reflected also in this section.

See comments below regarding consent / assent for children.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Section 8.26 - 8.33: There is a lack of consideration for the burden placed on unwell children to provide assent (or consent if considered 'capable' in terms of maturity). There needs to be acknowledgement that in many cases children being considered for a clinical trial are actually unwell (sometimes very unwell and/or post-anaesthetic, and/or traumatised by being in hospital, the clinical procedures being undertaken, and distress in family members). Therefore the possibility of a reduced capacity for understanding, and the unnecessary burden of asking the child to review documentation and consent/assent should be an additional and important consideration. In most cases the child will need some form of treatment regardless of trial participation, and in many cases the non-trial treatment will be very similar to the trial option.

Regarding written assent forms: In practice the use of assent forms in children under the age of 10 years, particularly those who are acutely unwell, is frequently impracticable. The most common outcome we have is that the child just doesn't want to engage as they are not physically or psychologically well enough to do so. The imperative to create suitable assent forms is good in theory, but the practice doesn't necessarily stack up. I note that many/most Australian states do not require written assent from those unable to consent for themselves.

Of note, agreement from ethics committees on what form assent forms should take is one of our biggest issues. As is the question of 'pictures' or 'no pictures' we had previously been directed to remove cartoons as they were considered coercive, but are now being asked to put them back. But the nature of said cartoons / pictures is not advised on.

I think this whole issue needs more common sense discussion and direction from NEAC that allows for a more study by study determination of the appropriateness of seeking assent from potential child participants.

## **Informed consent**

**The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)**

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

The requirements are quite hard to follow and are contradictory - particularly where sections 9.29 - 9.32 are viewed against section 9.34.

It is not uncommon for us to have comments from clinical staff, families and ethics committees that our information sheets are too long - but fitting all of the required information leads to such long forms. I think there needs to be more common sense direction from NEAC on this.

**The section covers all relevant ethical issues and or principles for health and disability research in New Zealand**

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

See statement above.

### Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

#### Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

### Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

13.19 - see comment below

13.48 - I disagree with Table 3 in terms of the 'imperatives for phase 1, 11a trials and non-randomised trials. I also disagree with the determination of need for DMC.

### Charging participants

**Please outline your reasons:**

I do not believe that New Zealand should allow any situation in which participants can be charged to participate in trials. I would see this as a very 'slippery slope' to a greater level of inequity, and the potential for poorly designed trials to be run here.

### Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

14.23 - the wording is confusing here. and I think there may be typographical error.

Big data and new ways of using data

Not Answered

**Please provide feedback:**

### Human tissue

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Section 15.22 - there should be some recognition that some tissue samples provided in clinical trials are tested and reported for a purpose that is fed back to the clinical team and in some way determines or directs treatment - ie sub-group of diagnosis, risk group etc. In this case the need for clinical safety via use of full identifiers should override concerns over data breach - in the USA this is not considered a HIPAA violation as the result will directly impact on patient treatment. This aligns with normal clinical sample identification where a clinician needs to be assured that the correct result and correct patient are clear. If this is clearly stated in the PICF this should be considered safe care and safe research practice.

<b>Response number</b>	<b>5</b>
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Disagree

#### Please outline your reasons:

Please see the comments on the stem cells section in which this is not the case.

The standards are applicable to all types of health and disability research  
Disagree

#### Please outline your reasons:

The stem cell section of the document has not considered a number of current research scenarios currently being undertaken in New Zealand.

The standards balance protecting individuals with the realities of conducting research  
Disagree

#### Please outline your reasons:

The stem cell section of the document does not distinguish between the use of stem cells for research into basic biological mechanisms, and the use of stem cells for therapeutic applications. These have very different ethical implications for protecting individuals.

The standards support researchers to navigate ethical challenges in health research  
Neutral

#### Please outline your reasons:

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:**  
Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:**



Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Neutral

**Please describe the ethical challenges that are missing:**

In general, the standards do this for most aspects. But they do not adequately cover the ethical challenges relating to stem cell research.

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Neutral

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Not Answered

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Human tissue**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Clause: 15.48 Currently, the Human Assisted Reproductive Technology Act 2004 substantially limits gene editing research in New Zealand.

Comment: The intention of this clause relates to gene editing of viable embryos, but is phrased in a non-specific context.

Suggested rewording: 15.48 Currently, the Human Assisted Reproductive Technology Act 2004 substantially limits research involving gene editing of viable pre-implantation embryos in New Zealand.

## Research with stem cells

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

We do not believe that Section 17 is fit for purpose for three major reasons:

- 1) It is overly simplistic, meaning that it does not encompass the breadth of types of stem cells or tissues from which they are derived, nor does it specifically define a number of terms that could be open to numerous interpretations (e.g. 'product', 'stem cell lines'). We would suggest that a definitions sub-section is required within Section 17.
- 2) While describing a clear intent not to do so the section mixes the use of stem cells for research purposes only (i.e. to understand fundamental biological mechanisms), with stem cells being used for clinical research/therapeutic applications. This is an extremely important distinction, with very different ethical consequences and the guidelines for research and clinical use of stem cells must be much more distinct. We suggest two separate subsections.
- 3) It lumps together human embryonic stem cells, fetal stem cells, and embryonic germ cells derived from fetal tissue into one broad category, which is extremely misleading. Indeed the words embryo and fetus have specific definitions (relating to gestational age) and the words are used incorrectly in this section. The definition of fetal is considered to be  $\geq 8$  weeks post conception, and in this document the boundary between an embryo and a fetus needs to be clearly defined. At what stage of gestation is a cell line considered to be embryo derived? This is particularly critical when considering work employing placental stem cells, or cells from the placental membranes such as amniotic epithelial stem cells, as the placenta is a fetal organ. At term, in most jurisdictions, the placenta is discarded as biological waste, and thus is generally considered to provide an important ethical source of stem cells with a wide range of potential therapeutic applications. If derived from an early gestation placenta, such placental stem cells might under the current wording be defined as embryonic stem cells. That is clearly not the intention of the

guidelines as embryonic stem cells are derived from the pre-implantation blastocyst, a stage of embryonic development at which the placenta does not yet exist. The use of placental stem cells, or generation of placental stem cell lines, is clearly a very different ethical scenario from the creation of embryonic stem cell lines. However, in this document no distinction is made. Finally, the trophoblast (the outer layer of the pre-implantation blastocyst that forms the trophoblast lineages of the placenta, (but does not contribute to the cell content of the embryo proper) is not considered. As there is work currently underway on trophoblast stem cells this must also be taken into consideration in some way by the guidelines.

Whilst we have made specific comments regarding individual clauses below, and recommendations for rewording, we believe that the entire section(s) relating to human stem cell research and therapeutic use needs to be completely rewritten as the current draft is based on an overly simplistic understanding of our current knowledge. The section needs to contain definitions of 1) what is a cell line, 2) what are the various types of stem cells (multipotent, totipotent, pluripotent, progenitor etc) 3) what is an embryo pre or post implantation and what is a fetus or fetal-derived lines etc. The standards governing therapeutic and research need to be completely separated as appears to be the intent but not the reality of the draft. If this recommendation is accepted we are willing to assist in completely redrafting these sections.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Clause:

17.5 The four main types of tissue that can be used to create stem cell lines are:

- adult adipose tissue
- cord blood
- bone marrow
- induced pluripotent stem cell lines that could come from any somatic tissue.

Comment: Adult stem cells can be, and have been, derived from almost every organ in the body. The list described here is extremely limited in scope, to the point where the statement is completely inaccurate and entirely misleading and must be changed to reflect the current knowledge.

Suggested rewording:

17.5 Stem cell lines can be created from a wide range of tissues, including:

- adult tissues (e.g. bone marrow, adipose tissue, gut, kidney, liver, endometrium)
- fetal tissues (e.g. cord blood, placenta, fetal membranes, umbilical cord)
- the inner cell mass or blastomeres of embryos (e.g. especially human embryonic stem cells)

- the generation of induced pluripotent stem cell lines that could come from any somatic tissue or germ cell.

Clause:

17.6 All research concerning stem cells must comply with relevant legislation and guidelines

Comment: It is unclear what legislation and guidelines are being referred to here. Please specify (for example, the ISSCR guidelines for stem cell research and clinical translation, published 12/5/2016, and available at [www.isscr.org](http://www.isscr.org)). We would also recommend that this guideline be explicitly listed in clause 17.18.

Clauses:

17.8 Researchers creating a stem cell line must obtain informed consent for future use of tissue separately from informed consent for clinical treatment.

17.9 Research involving the development of new stem cell lines must be scientifically justified. It must also be conducted (and peer reviewed) by individuals with appropriate expertise.

Comment: We would like to raise two distinct issues with these clauses:

1) In both of these clauses it is imperative to define what is considered a stem cell line. Stem cells from adult tissues are routinely isolated and cultured for several passages in basic biological research. Such cells are not immortalised lines in the traditional sense, and generally slow down their rate of proliferation and reach senescence within 10-20 passages. When is such a cell considered to be a cell line? Furthermore, many cells in the body are multipotent, and their differentiation potential lies across a broad spectrum ie they may be able to give rise to only one or two differentiated cell types, or alternatively they may give rise to multiple types of differentiated cells. Other so-called stem cells give rise to only a single differentiated cell type (eg endometrial epithelial stem cells – extremely potent stem cells in the female reproductive tract, and spermatogonial stem cells in the male testis that give rise to sperm). Therefore, where is the line drawn between a the isolation of a population of primary cells from a particular tissue that may be able to form more than one downstream cell type (of which many are routinely isolated from a range of adult tissues and currently in clinical trials), and a ‘stem cell’ line that may be able to form multiple types of differentiated cells? This is not a trivial question within the stem cell biology field where the distinction between progenitor cells and stem cells is a very important one that is widely debated. 2) The use of such cells for basic biological research is distinct from the use of cell lines for future human therapeutic applications, and no distinction is made for these separate downstream purposes here.

Suggested rewording:

17.8 Researchers creating a stem cell line for clinical use must obtain informed consent for future use of tissue separately from informed consent for clinical treatment.

17.9 Research involving the development of new stem cell lines for clinical use must be scientifically justified. It must also be conducted (and peer reviewed) by individuals with appropriate expertise.

Clause: 17.10 For products derived from pluripotent stem cells, researchers must plan to minimise persistence of any remaining undifferentiated cells in the final product and demonstrate that these cells do not result in tumours in long-term animal studies, where appropriate.

Comment: Please define what is meant by a 'product'.

Clauses:

17.11 Before any research begins, researchers must establish the specific risks and benefits associated with stem cell research. In addition, they must adopt practices that address long-term risks associated with the procedures.

17.17 Research with stem cells may be associated with specific risks (such as cell contamination). Researchers must consider these risks in advance of their research and address them in any protocols.

Comment: Without explicitly stating so, we believe that these clauses refer to the clinical use of stem cells. In this case we entirely agree that a careful risk benefit analysis should be undertaken and long term risks considered. However, the use of stem cells for basic biological research does not have the same set of risks (either short term or long term), and therefore it is important to explicitly state the intended scenario in the clause.

Suggested rewording:

17.11 Before any research employing stem cells for therapeutic use begins, researchers must establish the specific risks and benefits associated with stem cell research. In addition, they must adopt practices that address long-term risks associated with the procedures.

17.17 Research employing stem cells for therapeutic use may be associated with specific risks (such as cell contamination). Researchers must consider these risks in advance of their research and address them in any protocols.

Clause:

17.16 Where stem cell lines are proven to have therapeutic benefit, researchers should distribute them to the appropriate research community to use.

Comment: We are concerned that the use of the term 'distribution' implies that researchers that have created an effective cell therapy would be expected to give this away in a not-for profit manner, and relinquish any rights to the intellectual property or patent/s associated with such a product. If this were the case, this would have an extremely negative impact on commercial investment in research within New Zealand, and is unprecedented in other developed countries.

Suggested rewording:

17.16 Where stem cell lines are proven to have therapeutic benefit, researchers should distribute them to the appropriate research community to use disseminate this information as widely as possible.

Clause:

17.22 Embryonic stem cell lines are difficult to create and require viable embryos as a starting cell system. In New Zealand, it is yet not permitted to create stem cell lines from viable human embryos. Embryonic stem cell lines for research must be imported from overseas. The standards in this section apply to various types of research on human embryonic cells and fetal cells, and embryonic germ cells derived from fetal tissue. Institutions and researchers conducting basic research with these human biomaterials should follow the standards to the extent that they relate to the following categories:

- deriving human embryonic stem cells
- banking, distributing and making preclinical use of embryonic stem cells
- obtaining human embryos, gametes and somatic cells for stem cell research and in-vitro embryo studies.

Comment: Embryonic cell lines and fetal cell lines are not the same thing, and should not be grouped together in the same context. Human embryonic cell lines are derived from cells of the inner cell mass, or cell that will become the inner cell mass of pre-implantation embryos, and the HART act states that this is not permitted in New Zealand. However, post implantation embryonic or fetal stem cells derived from the placenta, cord blood, or fetal membranes can ethically and legally be isolated and used for research in New Zealand, from any gestation post implantation. We believe it is the intent of the document to provide regulations around the use of human embryonic stem cells in this section (as in keeping with the section title “Embryonic stem cell research”), and that this should be more precisely defined in this context as “human embryonic stem cell lines”. It may be appropriate to include separate provisions/clauses referring to fetal tissues to explicitly define what is and is not considered ethically acceptable (for instance, currently approval is granted for the use of placenta, cord blood and fetal membranes, but not for the use of cells derived from the embryo-proper). It is also important to distinguish cell lines derived from the trophoctoderm of the preimplantation blastocyst (the cells of the outer layer of the blastocyst which contribute only to the formation of the placenta and not the embryo proper) from “embryonic stem cell lines. Trophoctoderm cell lines can be derived from non-viable blastocysts (ie those lacking an inner cell mass) and this is not prohibited by the HART Act. Such cell lines are extremely valuable in pregnancy research.

Suggested rewording:

17.22 Embryonic stem cell lines are difficult to create and require viable embryos as a starting cell system. In New Zealand, it is yet not permitted to create stem cell lines from viable human embryos. Embryonic stem cell lines for research must be imported from overseas. The standards in this section refer to various types of research on human embryonic cells and fetal cells, and embryonic germ cells derived from fetal tissue. to cells derived from the inner cell mass of pre-implantation stages of development. Institutions and researchers conducting basic research with these human biomaterials should follow the standards to the extent that they relate to the following categories:

- deriving human embryonic stem cells
- banking, distributing and making preclinical use of embryonic stem cells
- obtaining human embryos, gametes and somatic cells for stem cell research and in-vitro embryo studies.

Clause:

17.24 All research that involves pre-implantation stages of human development, human embryos or embryo-derived cells must be subject to ethical review, approval and ongoing monitoring by the Ethics Committee on Assisted Reproductive Technology. It must also address the uniquely sensitive elements of human embryonic stem cell research.

Comment: In its current form, this clause is not specific enough as the pre-implantation stages of human development may be studied indirectly via proxy cell based models (e.g. by using trophoblast cell lines to study adhesion to the endometrium). We recommend explicitly stating that this clause refers to cells derived from the embryo as below. The trophectoderm has also not explicitly been considered in this section, and we believe that it is imperative to ethically separate out totipotent and pluripotent cells obtained from the morula and inner cell mass from other extra-embryonic lineages such as the trophectoderm that have a much more restricted differentiation potential and do not contribute cells to an individual .

Suggested rewording:

17.24 All research that involves totipotent or pluripotent cells derived from the inner cell mass of pre-implantation stages of human development, human embryos or embryo-derived cells must be subject to ethical review, approval and ongoing monitoring by the Ethics Committee on Assisted Reproductive Technology. It must also address the uniquely sensitive elements of human embryonic stem cell research.

Clause:

17.27 Researchers performing derivations of embryo-derived cell lines must have a detailed, documented plan for characterising, storing, disposing of, banking and distributing new lines.

Comment: This clause highlights the importance of defining the distinction between stem cells derived from the embryo, and fetal cells. For instance, is it a requirement that all cell populations isolated from the placenta are subject to this high level of monitoring? We do not believe that this is the intention of the document. Furthermore, as for clause 17.24, the trophectoderm needs to be either explicitly included or excluded from this clause.

<b>Response number</b>	<b>7</b>
Name	[redacted]
Organisation	[redacted]
Role	Research director
Interest group	Health service provider
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable

Agree

**Please outline your reasons:**

The standards are applicable to all types of health and disability research

Agree

**Please outline your reasons:**

The standards balance protecting individuals with the realities of conducting research

Agree

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research

Agree

**Please outline your reasons:**

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree



**Standards - help researchers give due consideration to local and national community views and perspectives:**

Neutral

**Standards - protect and reassure the community:**

Neutral

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Disagree

**Please outline your reasons or suggested improvements:**

I think that the threshold between research and non-research should be better defined. Although that's probably impossible, I think that a good operational definition should be, 'Does the project required Ethics Committee review?' From there, you could link to HDEC guidance

(<https://ethics.health.govt.nz/hdec-review-and-approvals/find-out-if-your-study-requires-hdec-review>), and then write something like,

If your project requires HDEC review, then all of these NEAC guidelines must be followed. If your project does not require HDEC review, then these NEAC guidelines should be followed as applicable. If you are unsure whether HDEC review is required, please complete an HDEC Scope of review form on the HDEC website.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

4.6 and 4.7 are what I was referring to above. I actually think all of the activities in the box in 4.6 ARE research. Just, 'research with a little r', and those projects should be approached with the same ethical standards as a Phase 3 RCT. That's why I say that a threshold should be defined, and I think it should be the threshold for whether it warrants HDEC oversight. Same with 4.7-- innovative practice likely warrants ethical rigour, even if it doesn't necessitate HDEC oversight.

I feel it would be very helpful to write an appendix or resource document aimed primarily for a CLINICAL audience, that gives examples for what does/doesn't cross the threshold. For example:

a busy doctor wants to publish a journal article, and plans to retrospectively review twenty of his patients' medical records on the effectiveness of X intervention. Does he need to submit to HDEC? Does he need to seek consent from each of those patients? (Does it depend on his method of data presentation?)

I think that giving that clarity would be really helpful for clinicians who don't often venture into the world of 'Big-R Research' and might otherwise end up overwhelmed and mis-interpreting these guidelines.

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Figure 1. I thought at first Tika = beneficence, mana = justice, and so on. But they are 8 individual / inter-related concepts. I think it should be made into a circle with spokes, and two coloured halves for the Te Ara Tika vs bioethics.

I think this should come earlier in the guidelines. These should be pointed out that studies should consider/ meet all of these principles, and that each of these principles should be considered when 'troubleshooting' a protocol/project or considering the unintended consequences.

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback**

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

**Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

**Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Can the benefits and harms in 14.2 be combined with this section? Something will be overlooked if parts are in two different sections.

**Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

There was no option for this section, but I refer to section 3.12. All of the following definitions should be indented from there, e.g., 3.12.1, 3.12.2, etc.

3.19 and 3.20 should include sub-investigators, research coordinators, research nurses, research assistants, etc. It's not only just someone with 'researcher' in their job title-- often even receptionists get tasked with some day to day research activities and they must be compliant too.

3.19 and 3.20 should also include contract research organisations-- often hired by the Sponsor and work in the PI's clinic (ostensibly under the PI's oversight, but independently in many instances). It should be noted that even if the CRO is a local franchise of an overseas company, that NZ guidelines would apply to all that they do.

3.22 should note that the Sponsor many times fully designs the study (and the Sponsor can be overseas, re: Maori / Pacific collaboration) and that the Sponsor can take responsibility for study quality monitoring (taking it out of the hands of the PI and research nurse).

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

#### **Please outline your reasons why the section is or is not fit for purpose:**

Nearly the entire commentary section can be deleted. Surely, researchers who have the capacity to plan studies with these designs do not need a lecture on research methods. The Guidelines should only include 'should or must' statements (and necessary supporting information). If desired, the categories of studies could be listed in bullet-points with the commentary section moved to an appendix or into the online definitions.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

#### **Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

#### **Please provide feedback with reference to the paragraph(s) in question:**

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

#### **Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

#### **Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

13.12 add 'for instance, www.xxxx'

A lot of the activity in 13.16 and onward may be determined / controlled / completed by the Sponsor, not the PI (study monitoring, AE adjudication, data analysis, drafting publications). The PI may simply passively agree to it. If the Sponsor is overseas, how would the NEAC guidelines be assured to be followed? **Charging participants**

**Please outline your reasons:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

The title is wrong. To me, 'compensation' = 'payment' and I thought it was about koha to the subject as a thank-you.

But you mean 'If a participant is injured while they are a subject in a study, here are the standards for making it right'.

This whole thing needs to go into the Informed Consent section because 'What if I am harmed during the study?' is a standard section of an ICF.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

<b>Response number</b>	<b>8</b>
Name	[redacted]
Organisation	[redacted]
Role	Researcher
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:**  
Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**  
Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Fit for purpose because it clearly sets out the rationale for using a principles-based ethical standards framework. It provides a concise description of each of the sets of four principles (of Te Ara Tika and of Bioethics) and what needs to be done to satisfy each. Recommendation: that clause 5.3 includes citations in support of the position that 'bioethics principles are widely recognised'.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section is largely fit for purpose (as per the description above). However, there is capacity for further enhancement. Specifically, for example:

- clause 6.11 line 4 : substitute MUST for "should". In doing so consistency with 6.10 would be better achieved.

- clause 6.12 line 3 : substitute REQUIRED for "preferred" (setting further clarity around ethical practice requirements).

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

6.17 Consultation - cultural sensitivity and understanding are not acceptable substitutes for Māori participation at all stages of the research. Throughout this section (Research Involving Māori) the use of the term 'consultation' should be critically considered with a view to replacement with the concept of participation to better align with the Treaty principles previously highlighted in the document.

6.14 considers what makes consultation 'adequate' in the context of Research involving Māori. The content of 6.14 needs to sit at centre stage rather than being 'lost' in the sub-section on Engaging and Consulting Early.

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Neutral

**Please provide feedback with reference to the paragraph(s) in question. :**

6.17 Consultation - is weak for reasons including that it does not define the central concept of consultation. In practice, consultation tends to be interpreted in a variety of ways. It may be believed to be opportunity to contribute to decision-making, at one extreme, or as mere tokenism at the other. The wording of clause

6.19 implies that 'consultation' means lip service only. Substituting "WILL MAKE EVERY EFFORT" for "try to" and deleting the words "as much as possible" may strengthen clause 6.19.



Box 1 Kaupapa Māori Research - macrons missing in the Minimum Expectations section. Add citations to the Kaupapa Māori definition section. Add that a Kaupapa Māori approach may, on its own terms, draw on Western methods etc.

Ethnicity Data Collection 6.24 - Begins with a very broad claim that requires (1) modification e.g. much district health board (DHB) level data poorly evidences capture of ethnicity data. Additionally, data analysis capacity and capability is uneven across the DHBs (2) adequate citation. Recent ethnicity data protocols need to be cited.

### Research involving Pacific peoples

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

#### **Please outline your reasons why the section is or is not fit for purpose:**

Easy to follow / understand and provides some practical guidance. In places, the introduction and standards this section includes require strengthening which could be simply achieved (refer below). Strengthening is especially necessary if the the standards are to adequately reflect the equity issues the ethical principles themselves support.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

#### **Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

#### **Please provide feedback with reference to the paragraph(s) in question:**

7.4 Use of term 'consultation' is problematic because it is not defined here and there is room for uncertainty regarding intent as a result.

7.12 Substitute MUST for 'encouraged to'

7.13 Substitute MUST for 'should'

7.16 Substitute MUST for 'encouraged to'

7.17 Clarify what the term 'consultation' means in the context of this standard (does it mean meaningful opportunity to contribute to decision-making? paying 'lip service' to the community and 'ticking a box'? something else?).

7.18 Substitute MUST for 'should' x2

### Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section is easy to understand and provides sufficient guidance to inform decision-making.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research with participants who are unable to consent**

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

Yes

### **Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

No comment

### **Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

11.9 Line 4 - substitute MAY for 'are' (generalisability, for example, MAY NOT be an important aspect of a particular study's scientific value).

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

13.12 Clarify that this standard is not universally relevant.

13.75 Line 4 : To ensure consistency with the principles underpinning the standards, substitute MUST for 'should'.

13.76 Line 2: Insert the words ",in decision-making roles," immediately after the words "Including Māori researchers.

Charging participants

**Please outline your reasons:** No comment

## Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Big data and new ways of using data

Agree

**Please provide feedback:**

## Databanks

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Human tissue

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

15.4 Bullet point 4 : The term 'consultation' is again used and referenced back to Chapter 6 Research involving Māori 6.11 - 6.20.

6.20 : Identifying 'degrees' of consultation fails to consider ability to PARTICIPATE in decision-making and to clarify the differences between consultation and participation. These points are best covered in 6.14. It would be useful to elevate 6.14 to a focal point in Section 6.

### Biobanks

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research with stem cells**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

<b>Response number</b>	<b>9</b>
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Consumer
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

But some sections could be stated more simply: p10 para 2.8 'health inequities' is unintelligible.

Some are too broad to provide real guidance: p18 para 4.16 innovative practice - what is appropriate time and appropriate way?

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:** Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:** Neutral

**Standards - protect and reassure the community:**

Neutral

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Neutral

**Please describe the ethical challenges that are missing:**

P53 para 9.86 additional protections - not clear what happens where persons interested in participant's welfare do not agree on participation eg. siblings or parents disagree.

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

Distinction between Funder and Sponsor unclear.

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree



**Please outline any missing ethical issues or principles:**

P36 para 8.30 Many participants though aged 16 or over would find it difficult to provide their consent particularly for serious procedures. They would prefer to be guided by parents or older persons, and some may not want to be briefed at all. I had personal experience of this with a child aged 16+ being treated for leukaemia. He delegated all decisions to me, and generally communicated with his doctors through me. He did not wish to have the burden of hearing different options or making decisions as the illness was already overwhelming.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Para 8.30 - allow child aged 16-18 to delegate medical decisions to named adult (see above).

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

Para 9.86 - interested parties may disagree on participation or other options for adults unable to consent. Guidance is unclear about how to handle this.

Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

These principles appear reasonable.

**Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

P63 para 11.21 skills and resources of researchers.

inequalities experienced particularly by Maori - what about Pasifika peoples? appropriate skills and resources to deal with unexpected events - especially adverse ones.

**Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

P77 para 13.47 members of Trial Management Group should include consumer representative/s or lay persons or members of community who are able to provide a view representative of the community. This aspect seems absent from these Standards, which may signal to researchers that omitting consumer representation from research studies is acceptable.

Charging participants

**Please outline your reasons:** Yes

<b>Response number</b>	<b>11</b>
Name	[redacted]
Organisation	[redacted]
Role	Senior Lecturer
Interest group	Academic
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

On the whole the standards seem clear but I felt the CRISPR section was really limited.  
No reference to editing of ex-vivo tissue such as blood cells and skin cells

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Neutral

#### Please outline your reasons:

I think so - time will tell...however, some sections such as Maori consultation say you should consult with Maori but no direction about how to go about that - what constitutes 'good' consultation?

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:** Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Strongly Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Neutral

### Coverage of ethical guidance

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

More about CRISPR

My other issue is around inclusion. I sit on a Biological ethics Committee and most BSC applications exclude working with maori DNA - this is at odds with the inclusivity which is suggested in the ethics standards.....

### Merging the observational and interventional guidelines

The standards are applicable to both observational and interventional research

Neutral

**Please outline your reasons:**

### Scope of the standards and non-research activities

**Is the scope of the document clear?**

Neutral

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### Research involving Māori

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Not Answered

**Please provide feedback with reference to the paragraph(s) in question. :**

<b>Response number</b>	<b>12</b>
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Academic
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

**Please outline your reasons:**

The standards are applicable to all types of health and disability research  
Agree

**Please outline your reasons:**

The standards balance protecting individuals with the realities of conducting research  
Agree

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research  
Neutral

**Please outline your reasons:**

I think researchers need to establish these skills and knowledge before navigating the standards.

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:**  
Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Neutral

**Please provide feedback with reference to the paragraph(s) in question. :**

I value strong collaboration with Māori in the production of research in New Zealand. However, I have problem with the section in the Information Sheet template that states "For Māori health support please contact:" It's not clear what cultural background or cultural training is required for this role. It's is also not clear how involve this person has to be the development/delivery of the research. There is an implication in this line that all research studies MUST include a Māori co-investigator, who is fully familiar with the project and culturally competent to address cultural issues that arise for any potential participant. If this is the intent, it ought to be clearly stated in the Standards - and some consideration also needs to be given to the impact this requirement would have on resourcing in research institutes. (This would have substantial cost implications if it were the case.) If this is not the intent, then the Standard should clarify what actually are the expectations of this role and what purpose it serves. There is a tension here between ideal level of Maori involvement in research nationally, and what NZ institutions can realistically provide resourcing for. But I am also concerned that currently this expectation just results in higher burden on Maori staff in research organisations (being asked to do more work for no extra pay), with little benefit to them personally, and only token benefit to Vision Mātauranga. I think in NZ we need up our game in term of Māori leadership in research and senior research positions, but I don't think this expectation of requiring ALL research project include a Maori health support contact addresses this need.



<b>Response number</b>	<b>13</b>
Name	[redacted]
Organisation	[redacted]
Role	Scientist
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable

Neutral

#### Please outline your reasons:

All Te reo should be defined in text. It is very hard to read when you need to keep checking definitions. This is a complex and important document. There maybe additional ways of splitting up text and clarifying parts unsing diagrams or flowcharts to help some readers whom are more visual.

The standards are applicable to all types of health and disability research

Neutral

#### Please outline your reasons:

They appear to have good coverage of the research that my organisation conducts.

The standards balance protecting individuals with the realities of conducting research

Agree

#### Please outline your reasons:

All standards appar very reasonable for our organisations research. However, we generally do not conduct studies with vulnerable people and do not use pharmaceuticals or hold trial that pose considerable risks to our participants e.g. complex medical procedures.

The standards support researchers to navigate ethical challenges in health research

Agree

#### Please outline your reasons:

I found many sections very useful abd the document helped put a new prespective on our research processes. I would certainly be recommending this as a go to document for anyone looking into conduction human clinical trials.

### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:**

Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Neutral

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

A large variety of ethical aspects are covered. However, this is a hard document to read and there maybe ways to make sections easier to read by added summaries, boxes with key points, flowcharts and diagrams.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

## Ethical principles

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

This section provides a good overview and is a good setting for the following sections.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

## Research involving Māori

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

This section highlights the importance of early Maori consultation and constant engagement with Maori throughout the clinical research.

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

## Research involving Pacific peoples

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

This section is very vague on what a researcher should be doing. Our research involves all ethnicities and we attempt to engage all, but only consult with Maori representatives specifically. Should we not be trying to engage all ethnicities equally to represent the true diversity of New Zealand?

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

If we were to attempt to engage all ethnic groups present in NZ it will become very difficult to ensure that everyone's cultural beliefs are considered. Maybe general guidance on ensuring that everyone is treated with respect and equally regardless of ethnicity is what is required here and then generalising the section to all ethnicities represented in NZ?

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

Some parts are clear e.g. Research in children and young people and pregnancy. However, some parts are vague and it is unclear what a researcher should be doing to engage with potentially vulnerable people.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Informed consent

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:** ction covers many aspects of informed consent. It can be very hard to read in places. However, this could be due to

not being familiar with the types of studies involving vulnerable people or higher risk studies myself. This section could benefit from checklists and diagrams to aid the reader.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

Yes. This is a difficult area to address. My personal belief is that work should be allowed to be conducted when informed consent cannot be obtained if the benefits to the participant outweigh the risks. However, this should be closely monitored and dealt with on a case by case basis.

Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

I am not involved in research using deception techniques and cannot comment with personal experience. I believe that it would be necessary to use deception in some studies and when it is justified, reviewed and accepted by an ethics committee, the research should be allowed.

**Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

A good overview to think about the risks and harms of the proposed research.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

**Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

This section is clear and concise.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

This section would benefit from diagrams to help explain study designs.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

A very good section for newer researchers.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Charging participants

**Please outline your reasons:**

I don't feel qualified to comment. It does not seem ethical to stop people from participating due to their financial status.

**Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

This section raises some interesting considerations for designing new studies.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Big data and new ways of using data

Agree

**Please provide feedback:**

However, each case should be considered individually. People are becoming more aware of their data being shared inappropriately via social media and data leaks. It is good to have clear mechanisms in place for re-using and linking data, such as removing all identifiers.

**Databanks**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

This section includes some key considerations for making provisions to protect participants data in databanks. This is an area researchers have to consider very seriously with the move towards big data.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

***Please provide feedback with reference to the paragraph(s) in question:***



<b>Response number</b>	<b>14</b>
Name	[redacted]
Organisation	[redacted]
Role	researcher and lecturer
Interest group	Academic
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable

Agree

**Please outline your reasons:**

The standards are applicable to all types of health and disability research

Neutral

**Please outline your reasons:**

The standards balance protecting individuals with the realities of conducting research

Neutral

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research

Disagree

**Please outline your reasons:** it does not fully address all ethical issues **Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Neutral

**Standards - reflect the principles of the Treaty of Waitangi:**

Neutral

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Neutral

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Neutral

**Please describe the ethical challenges that are missing:**

Not all aspects covered, specific to non maori

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

Too much emphasis on The Treaty of Waitangi and not necessary fir for everyone

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

While involvement of Maori is important, it often seen as a must do for political reason more for the safeguards for Maori

Often involving Maori means seeking their approval for something that does not directly involve Maori i.e. migrants

When consulting Maori many abuse this process and refuses to s called tick the boxes

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Disagree

**Please provide feedback with reference to the paragraph(s) in question. :**

Too much emphasis on the Treaty 3 Ps principles

This should be simplified

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

## Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

## Informed consent

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback**

No

**Please provide feedback with reference to the paragraph(s) in question:**

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft**

**standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes: Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

## Research benefits and harms

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Charging participants

**Please outline your reasons:** no charges

## Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Big data and new ways of using data

Agree

**Please provide feedback:**

## Databanks

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Human tissue**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Biobanks**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research with stem cells**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:** needs more protection for consumers

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**



<b>Response number</b>	<b>15</b>
Name	[redacted]
Organisation	[redacted]
Role	Senior Research Fellow
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable

Neutral

#### Please outline your reasons:

I have only read one section of the standards and cannot comment.

The standards are applicable to all types of health and disability research

Neutral

#### Please outline your reasons:

I have only read one section of the standards and cannot comment.

The standards balance protecting individuals with the realities of conducting research

Neutral

#### Please outline your reasons:

I have only read one section of the standards and cannot comment.

The standards support researchers to navigate ethical challenges in health research

Neutral

#### Please outline your reasons:

I have only read one section of the standards and cannot comment.

### Overall do the Standards?

#### Standards - safeguard the rights and interests of participants in research:

Neutral

#### Standards - promote high-quality ethical research for social, cultural and economic wellbeing:

Neutral

#### Standards - reflect the principles of the Treaty of Waitangi:

Neutral

#### Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:

Neutral

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Neutral

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Neutral

**Standards - protect and reassure the community:**

Neutral

### Coverage of ethical guidance

The standards adequately cover the ethical challenges that are present in health and disability research

Neutral

**Please describe the ethical challenges that are missing:**

I have only read one section of the standards and cannot comment.

### Merging the observational and interventional guidelines

The standards are applicable to both observational and interventional research

Neutral

**Please outline your reasons:**

I have only read one section of the standards and cannot comment. **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Neutral

**Please outline your reasons or suggested improvements:**

I have only read one section of the standards and cannot comment.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### Human tissue

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Section 15.42 and 15.44 require clarification.

For section 15.42, I was unclear what was meant by 'researchers should give participants the option of being notified of the existence of that information /the option or receiving information'. A process approach may be more helpful here, rather than a hard and fast rule (eg. the research design could include a plan of how this situation will be handled). An unintended consequence of being required to provide all potentially clinically relevant findings to participants may be unnecessarily concerning patients and creating additional burden for the health system .

For section 15.44 , it was unclear what was meant by 'collective groups'. Does this mean consulting with representatives, small groups or entire communities?

<b>Response number</b>	<b>17</b>
Name	[redacted]
Organisation	Cancer Society of New Zealand
Role	[redacted]
Interest group	Charity
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

Overall, it is a clear, comprehensive document that aligns with the Cancer Society's position. We have included some specific feedback on the individual sections below.

The standards are applicable to all types of health and disability research  
Disagree

#### Please outline your reasons:

Although the standards are applicable to most types of health and disability research, they do not take into account all types of health and disability research (see 'research benefits and harm' section). The standards should be amended to reflect this.

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

In general we agree, however specific comments on the sections have been detailed below (see 'categories of participants' section).

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

The guidelines are detailed, comprehensive and clearly laid out, thus should support researchers to navigate ethical challenges in health research.

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:**  
Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Strongly Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Disagree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Strongly Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

As noted in the document, it is very difficult to define research, however we think the definition is clear. It is good to see it is in line with international guidance.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

It might be useful to highlight that the principles and standards apply to individuals from all career stages (section 4.5).

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Disagree

**Please provide feedback with reference to the paragraph(s) in question. :**

6.12 states 'Engagement with Māori at an early stage is preferred'. This is inappropriate and contradictory to Te Ara Tika framework. It should read 'Engagement with Māori at the design stage is a must'.

Suggest 6.13 also includes:

"If the researcher is of non-Māori descent, the researcher must answer these questions first:

- Am I the right person to be doing this study?
- In what ways does my cultural position help or hinder this study?"

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

The standards are good. However, the importance of spirituality and religious beliefs in Pacific Communities, needs to be emphasised and is more than just beliefs and values.

There should be a specific requirement to involve Pacific researchers to assist growing the Pacific research workforce. It is ethically important to support the development of this workforce through involvement in research.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

7.3:

Pacific peoples should participate in all levels of decision-making about and implementation of the study, and dissemination of results.

7.7:

Researchers must understand Pacific dimensions of health ...., or being engaged with a pacific partner to provide this knowledge.

7.8:

Researchers must take protective measures to safeguard indigenous Pacific knowledge and knowledge holders appropriately.

7.11- 7.18:

More directive language required. Changing suggestive language like “encouraged” (e.g. researchers are encouraged to build their cultural knowledge) and “should” (e.g. and should ensure any Pacific peoples) to more directive “must” statements so that researchers are required to be aware and understand these issues, or have a partner who works with them to ensure they are addressed.

## Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

It is very difficult to be able to cover all potential vulnerable groups – therefore it is important to have clear principles of participation that are adaptable to multiple groups including a clearer definition of “vulnerable”, what makes a specific group “vulnerable”. 8.1 does not provide enough clarity.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

This section does not clearly differentiate between research on/with vulnerable groups, and ensuring that vulnerable groups are not excluded inappropriately from general or wider research. Would benefit from addressing these issues separately.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

**Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

This document considers observational and interventional studies. The inclusion of only epidemiological criteria indicates a focus on clinical studies and the evidence 'hierarchy'. However, much preventive medicine/public health research is mixed methods and may involve quantitative and qualitative research. It would be good to be clear that different methods are used to answer different research questions and therefore have different ethics considerations. For example, a quantitative study may tell us how many Solomon Island women are accessing reproductive health care but the qualitative research will report rich data on key structural barriers and attitudes and beliefs that prevent access. Therefore we suggest the inclusion of qualitative as well as quantitative research and low-minimal risk/high risk ethics categories. The National Health and Medical Research Council doc is a good example of this (Ethical conduct in human research <https://www.nhmrc.gov.au/guidelines-publications/e72>). By not recognising mixed method/qualitative research and their specific ethics considerations is a failure to recognise or hold valid both national and global research undertaken by public health research institutions and organisations such as WHO and UNDP (as well as local NGO research).

This documents states that "health and disability research aims to generate knowledge to (1) prevent, identify and treat illness and disease (2) maintain and improve health (3) support people with disabilities to be included etc (4) address disparities (5) contribute to whānau ora. All these are aims of public health research that may not be able to be answered by observational (e.g. survey) or interventional (e.g. trial) studies – and these are the only two categories that are included in this document. This particularly applies to preventive health research and research to address disparities.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

Please see above.

Perhaps it would be useful to more clearly delineate levels of potential benefit and harm/discomfort especially if health ethics applications are to be considered by low/minimal or high risk ethics committees? Or is there no consideration to expedite low risk? Are low risk applications to go through the same process/committee as a likely higher risk randomised control trial, for example?



Perhaps if qualitative and mixed methods used in health research were explicitly included then this question may be considered?

i.e. could this document include some information on committees that applications will go to? Some information will help the ethics applications to be tailored to the specific committee, not only in levels of risk but also give the applicant an understanding of the expertise and focus of the committees – are they biomedically focused only? Are there committees focused on ethics considerations for social research methods? i.e. will the Cancer Society be able to progress an ethics application through a committee who can provide valuable feedback on a qualitative end of life study or is there one main committee that will be considering RCT's and descriptive research (for example)?

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:** As above

### Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

11.5 "Research should not exclude participants on the basis of their age, disability, sex, gender, ethnicity, nationality, religion, education or socioeconomic status, except where excluding or including them on these grounds can be justified for the purposes of the research". This should also include 'place of residence' and 'sexual orientation'.

11.6 "The researchers involved must have the necessary skills and resources to undertake the research." This should include '(or, if appropriate, be supervised by an appropriately skilled and resourced person)'

11.22 "Peer review may include considering cultural relevance and appropriateness." This should be "must" instead of "may".

### Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

This is a comprehensive and thoughtful section. Perhaps people undergoing cancer treatment and cancer survivors should be included as potentially vulnerable participants. 'People with incurable or stigmatised conditions or diseases' are already included and maybe this group could be expanded to include not only people with incurable conditions but also those with serious conditions, many of whom survive but still have particular research vulnerabilities.

e.g. people with cancer and other serious conditions may be vulnerable because they may accept risks that healthy people would not due to desperation. Or people who have survived cancer may be particularly vulnerable because of stress and anxiety arising from their involvement etc.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

**Charging participants**

**Please outline your reasons:**

**Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Overall, the section provides a good overview of ethical issues associated with the collection and secondary use of health information in research. It includes an excellent introduction, reasonable standards and very detailed commentary.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

The section needs to pay greater attention to the security and protection issues arising from advances in health information technology and the expanded collection and use of digital data. Those issues include - but are not limited to - possible access to IT technicians, data backups, virus and spyware protection and whether the data will be remotely accessible.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

14.10 Along with the support of a suitable person, conducting a consultation phase prior to the data collection could be an alternative or adequate option for new researchers.

14.37 There is a spelling mistake ('5esearchers' should be 'Researchers').

14.48 People with disabilities should be included as an example of vulnerable or disadvantaged groups.

Big data and new ways of using data

Agree

**Please provide feedback:**

We agree that the proposed standards in relation to data linking are reasonable and provide an adequate balance between protecting privacy and generating new knowledge.

**Databanks**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The databanks standards and its commentary section are both reasonable and fit for purpose.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

N/A – there are no missing ethical issues or principles.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

N/A

<b>Response number</b>	<b>18</b>
Name	[redacted]
Organisation	CHOMNZ/ NZ Prostate Cancer registry
Role	[redacted]
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

Broad and workable, focus on equity is good

The standards are applicable to all types of health and disability research

Agree

#### Please outline your reasons:

Am in Registry space and clear definition of opt out requirements

The standards balance protecting individuals with the realities of conducting research

Agree

#### Please outline your reasons:

Clear processes that protect privacy and security

The standards support researchers to navigate ethical challenges in health research

Agree

#### Please outline your reasons:

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Strongly Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

Informed consent: I believe we should consider a National alteration to all surgical consent ( and consent to treat ) with a line that indicates. "Patient data will be kept for quality and safety assessment and no patient identification will occur with use of this data.". This minor alteration will allow the collection and use of private and secure patient data for outcomes based registry and do away with the requirement for "opt out" consent.

Overall opt out is very low ( <5%) so not really useful however adds significant cost and time plus adds to ethics applications etc with no real gain.

This should be supported by all surgical groups including RACS plus all DHB's as measurement of outcomes is becoming vital at improving the value of health care.

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

Consider different process or waive consent in registry based de-identified outcomes projects

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Informed consent: I believe we should consider a National alteration to all surgical consent ( and consent to treat ) with a line that indicates. "Patient data will be kept for quality and safety assessment and no patient identification will occur with use of this data.". This minor alteration will allow the collection and use of private and secure patient data for outcomes based registry and do away with the requirement for "opt out" consent.

Overall opt out is very low ( <5%) so not really useful however adds significant cost and time plus adds to ethics applications etc with no real gain.

This should be supported by all surgical groups including RACS plus all DHB's as measurement of outcomes is becoming vital at improving the value of health care.

### **Research with participants who are unable to consent**

**Given the current legal environment, does the ethical guidance provided in the draft**

**standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes: No change required Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research: adequate**

## Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

This is mainly for clinical studies.

Design characteristics for outcomes registry would be useful so a blueprint, acceptable to National ethics plus then agreed by local DHB ethics is required. Currently both National and local ethics approval is required

## Databanks

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Excellent section and clear data processes

Response number	19
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Strongly Agree

#### Please outline your reasons:

The updated standards are a vast improvement on the prior standards. They offer clear, concise guidance across a wide range of topics, including new and emerging areas of research methodology. The working group have done an excellent job of putting these new standards together.

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The new standards are highly-applicable to all areas of my own research specialty (epidemiology).

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Strongly Agree

#### Please outline your reasons:

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Strongly Agree

**Standards - reflect the principles of the Treaty of Waitangi:**  
Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Agree



**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Strongly Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

Is the scope of the document clear?

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The standards explicitly state that they recognise He Korowai Oranga (the 2014 Māori Health Strategy) and the principles of Vision Mātauranga. Health inequalities and health inequities are defined – the definitions are a little hinky and could be improved, but at least they are there. Separate chapters are included on Māori health research and Pacific health research.

The standards bring together the principles of Te Ara Tika and principles of bioethics – these are the ethical sources that are used to set out the standards within the document – so are worth reading and understanding.

The standards now state that ‘Researchers must collect ethnicity data, unless there is a valid justification why it is not necessary.’ There are useful boxes that provide guidelines for consultation with Māori, including minimum standards that must be met.

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Excellent guidelines on vulnerable participants, including a section on managing unequal power relationships – everyone working with vulnerable populations should read them.

Also excellent guidelines on informed consent, including the information that researchers must provide participants with before gaining consent (it's a long list – we all need to read it).

Very interesting section on the integration on consent into normal clinical care – will impact more on clinical researchers, but opens up possibilities in terms of integrating research into normal clinical care.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

This is not my area of expertise.

Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

This is not my area of expertise.

**Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

**Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Contains guidelines on what a good study protocol should include – which is important when submitting ethics applications.

Contains some guidance on emerging/in vogue study designs, such as co-design/participatory research, cluster randomised trials, etc.

Chapter 13 on Research Conduct has a really useful one-pager on how a study should progress – worth printing and putting on the wall. The chapter as a whole includes specific guidance on things like approaching participants, methods of recruitment, etc. Includes a useful section on recruitment through social media.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Charging participants**

**Please outline your reasons:**

Yes, I think so.

## Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Big data and new ways of using data

Agree

**Please provide feedback:**

An entire chapter (Chapter 14) is dedicated to health data, including guidelines around data linking. Those working with the IDI or other linked data need to read this chapter inside and out, and become accustomed to the wording – since it will be the standard by which ethics applications are assessed in the very near future.

Importantly, the term ‘de-identified’ is being dropped from use in the standards.

<b>Response number</b>	<b>21</b>
Name	[redacted]
Organisation	[redacted]
Role	Lab head
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

**Please outline your reasons:**

The standards are applicable to all types of health and disability research  
Neutral

**Please outline your reasons:**

The standards balance protecting individuals with the realities of conducting research  
Agree

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research  
Agree

**Please outline your reasons:**

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:** Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**  
Strongly Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Neutral

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Human tissue**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

In my opinion, all genetic health research that involves follow-up with the participant should be carried out in association with a clinical specialist, such as a clinical geneticist, a genetic associate or clinical diagnostician. The standards listed in the draft document appear to be advising the researcher how to fulfil the role of a clinical specialist when discussing results with the participant and family members. What safeguards are there that cover the interpretation of the genetic findings? Discrepancies in the clinical classification of genetic findings between laboratories is common and I do not see the current standards protecting participants against well-meaning researchers reporting incorrect information. Without the involvement of a clinician it is likely that research innovation will be prematurely adopted into standard of care which is in contrast to 4.15. I often provide advice to genetic associates in NZ regarding the clinical classification of genetic



variants found in breast/ovarian cancer associated genes, however I would never give this information directly to my study participants.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Regarding 15.25

This suggests that researchers are obligated to inform participants on their results or incidental findings, which may not be consistent with the plan for how individual test results or incidental findings will be handled (15.24). Was this the intention? Biomedical researchers who refer their laboratory results to suitable health professionals may rightfully choose never to contact participants regarding clinically significant results as part of their study plan. Research findings are not equivalent to diagnostic findings carried out in a clinical setting which is highlighted in 15.42. Instead the researchers may allow the clinical specialist(s) to decide whether or not they wish to follow up on research findings and contact individual participants.

Page 94 footnote - This statement is unclear and seems unnecessary "Genetic research may involve the study of: gene expression, including environmental factors, pharmaceuticals and other therapeutic products".

Regarding 15.44

I understand the significance of this advice however it is unclear what genomic research this refers to. For example, whole genome sequencing provides a level of data could be used to derive information characteristic of hap■ or iwi, but researchers using this technology may not be carrying out research that leads to such information.

<b>Response number</b>	<b>22</b>
Name	[redacted]
Organisation	[redacted]
Role	Senior Lecturer
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable

Disagree

#### Please outline your reasons:

Although well written, the Standards document itself is too long. The majority of health researchers will not read them.

The standards are applicable to all types of health and disability research

Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research

Disagree

#### Please outline your reasons:

I have outlined my reasons in more detail in the "Informed Consent" section, but I believe the current information burden on participants has the paradoxical effect of them being less likely to understand the proposed study - in short, the Standards reduce the protection on individuals.

The standards support researchers to navigate ethical challenges in health research

Neutral

#### Please outline your reasons:

#### Overall do the Standards?

##### Standards - safeguard the rights and interests of participants in research:

Disagree

##### Standards - promote high-quality ethical research for social, cultural and economic wellbeing:

Neutral

##### Standards - reflect the principles of the Treaty of Waitangi:

Agree

##### Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Neutral

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Disagree

**Standards - protect and reassure the community:**

Neutral

### Coverage of ethical guidance

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### Merging the observational and interventional guidelines

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### Scope of the standards and non-research activities

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

As stated in paragraph 4.2 in the document, "It is not easy to offer a simple definition of research, or to provide a clear line between activities that are research and activities that are not." The reason it is difficult to provide a clear cut distinction between, for example, audit and non-interventional research into standard care is because there is no distinction in reality. I believe audit and non-interventional research should be treated identically for two reasons: a) Audit is clearly research - if the information contained within the audit were already know, then it would not need to be collected.

b) Audit and quality assurance activities are distinguishable only from non-interventional research in the intent to which the activity is performed – for audit, this is for local services, whereas for research this is to collect generalisable knowledge. However all research is limited by the data collected, with generalizability never guaranteed. Equally, “audit” can often provide generalisable knowledge, and publication of this should not be prohibited purely because it is not deemed research.

For these reasons, both should be held to the same standard of ethical approval. Ideally, given the low risk nature of retrospective research with an appropriate data governance policy, this could be a simple waiver from the ethics committee, or else a more streamlined expedited pathway should be provided. These reasons are largely in line with the opinions you received during your 2015 consultation. There should be no doubt that the administrative burden even of the current expedited pathway is a barrier to good research being carried out.

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Paragraph 9.34 documenting the information to be provided on the participant information sheet: I submit that the information burden on participants is too high. The presence of a participant information sheet (PIS) and signed consent form is not a reliable indication to a participant's understanding of the study. By putting all the information in a PIS, the length is so long that in reality the vast majority of participants never read the sheet. How many of us can truly say that we read the full terms and conditions when we sign up to a new website? Why would we expect study participants to be any different?

For low-risk studies, consideration should be given to a 1 page limit in bullet point form to allow participants to actually understand what the study involves. A link to a source of additional information could be provided on the simplified PIS.

Paragraphs 9.36 and 9.38, regarding specified and unspecified future use of data and tissue. It is unethical to place barriers (administrative or otherwise) in the way of research that has already been consented to. Section 9.36 should therefore not mandate that future research projects (using data and tissue where consent has been given for future use) need further ethical review. This is well established internationally, e.g. UK Biobank, the Genome-Tissue Expression project. Equally to maximize the value of these precious donations, there should not be a requirement for a specific duration of time for unspecified use of tissue or data (9.38) - to unnecessarily destroy freely given tissue and data that a participant has donated for research is unethical.

The information requirements in paragraph 9.38 are again too long and unwieldy. The addition of another PIS and consent form only contributes further to the information burden on the participant. The additional information is rarely viewed as useful by potential participants and frequently they seem surprised to be asked about it separately. It is very rare that someone consents to a primary study who then does not consent to future unspecified use of data/tissue. The overall effect is to make it even less likely that the participant will read any of the material provided.

Given the costs associated with collection and the scarcity of the samples involved, it is unethical not to maximize the potential knowledge gained from every research study. Therefore, there should be a strong recommendation that consent is gained for future unspecified use of tissue and data as part of every study unless there is a compelling reason not to. Given the complexities of the current PIS and consent form system, this should be done as a perhaps a few sentences in the PIS and a simple optional question on the same consent form.

### Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

#### Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

### Research benefits and harms

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

### Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

Paragraphs 11.15-11.17, regarding equal explanatory power. The wording here is unclear (to me, at least!). I read it as saying that there should be enough Māori participants to be analysed as a separate group with equal statistical power to non-Māori. This of course would put an end to the majority of clinical research in New Zealand - even in diseases overrepresented in Māori (such as diabetes), the number of participants required to adequately power a clinical outcome based study would be prohibitive unless the effect size was extremely large.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

<b>Response number</b>	<b>23</b>
Name	[redacted]
Organisation	[redacted]
Role	Professor
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

Clear, succinct and well written. Everything is where you would expect it to be.

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:** Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**  
Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Neutral

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Neutral

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No



**Please provide feedback with reference to the paragraph(s) in question:**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

10.34. "Researchers must provide participants with the following information, which will usually be in the form of a participant information sheet, as relevant:

.....

- whether the research findings may be commercialised and any ownership rights participants may have over these

Question is: what is implied here by ownership rights for participants? Is there a precedent here for ownership of i.p. when one is a participant for a study ? In commercially relevant research do we need to always clarify to a participant of their potential i.p. ownership or lack of in the patient info sheet ?

### **Research with participants who are unable to consent**

**Given the current legal environment, does the ethical guidance provided in the draft**

**standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes: Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

<b>Response number</b>	<b>24</b>
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Consumer
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

While the Standards are in general helpful, clear, relevant and workable we have an overarching concern that they appear voluntary and there is no mechanism for enforcing them. We have particular concerns regarding research conduct and the need for independent peer review and scrutiny both at the initial approval stage and as trials progress and data emerge.

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Disagree

#### Please outline your reasons:

The absence of an option to independently review a trial that is under way does not protect the rights of the individual. Similarly, leaving scrutiny and safety monitoring to those conducting the trial does not protect against conflict of interest.

The standards support researchers to navigate ethical challenges in health research  
Disagree

#### Please outline your reasons:

The absence of a mechanism to enforce the guidelines and to require the input of independent expertise to review a trial places the burden of ensuring safety and ethical status entirely on the researchers. The possible inclusion of an independent person on a Data Monitoring Committee is insufficient to protect both participants and researchers. There should be mechanisms in place that allow ethical and safety review that is entirely independent of researchers and sponsors of a trial. There is no mechanism for external stakeholders to prompt such a review during the course of a trial.

### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:**

Disagree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Neutral

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Neutral

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Disagree

**Standards - protect and reassure the community:**

Disagree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Neutral

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

This section contains the necessary elements

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Neutral

**Please provide feedback with reference to the paragraph(s) in question. :**

This should be undertaken in a more hapu, iwi and marae-based setting

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

8.12 should include people with poor health literacy and poorly educated people

8.32 after "proposed treatment" add "and its potential consequences"

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

There is no requirement for independent consumer and medical review of patient information sheets and consent forms. We have previously encountered forms that did not provide clear unbiased information to prospective trial participants, but were confusing and even misleading with respect to risk of harm to participants. The Breast Cancer Trials (Australia and New Zealand) model is a good one. All patient consent forms are reviewed by both clinical experts and trained consumer advisors.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Add a paragraph between 9.29 and 9.34 describing the need for independent medical and consumer review of information provided to prospective trial participants.

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft**

**standards provide clarity for the regulatory and ethical environment? NEAC notes that they**

**can revisit the ethical advice if the law changes: Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

### **Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

While we welcome the explicit discussion on the need to minimise harms to trial participants we note that there could be circumstances where patients may wish to engage in a high risk/high reward trial, e.g. with a novel immunotherapy treatment for cancer. Patients must be well informed of potential benefits and harms, but their own views should also be listened to and taken into account. Ultimately patients should be able to make their own decision about participation.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

The matter of self-determination is not included, see above comment.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

11.25 refers the reader to Committee on Publication Ethics Guidelines. This is not relevant or applicable to the the ethics of peer review of a study design.

Reference should be made to a relevant guideline here.

We note that SCOTT review is one New Zealand mechanism for peer review of clinical trials but their Terms of Reference do not cover ethical considerations.

More work needed here.

A scientific and ethical review by an expert panel should be required for all trials. A clear mechanism and process should be defined for this.

### Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

This section does not provide for independent review of the safety and ethical status of a trial that is under way. Neither does it require independence of members of Data Monitoring Committees. This does not sufficiently protect the integrity of the trial or the safety and wellbeing of trial participants from conflicts of interest likely to be present in researchers with a vested interest in the trial.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**



See above. There is insufficient provision for independent scrutiny of trials either at the approval stage or during the course of the trial.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

13.8 states that researchers must promptly report new information that may affect safety to regulatory bodies and participants. We agree but there should also be provision for external parties to present new information of this sort and have it investigated and acted upon. When we alerted the Northern B Ethics Committee of new information indicating ethical and safety concerns relating to a particular trial they ruled that they were unable to review the trial (in 2013) because it had received initial approval in 2007.

They stated that "Whilst the committees are responsible for checking that the appropriate review of the scientific merits of the study have been carried out prior to the study being approved, it is not the role of the ethics committee to conduct peer review". Therefore we conclude that there is no independent body that can assess the ethical or scientific validity of a trial that is under way, leaving patients exposed to harm.

13.45 to 13.48 All safety monitoring is or may be undertaken by researchers or individuals closely involved in a trial. There is no requirement for an independent review body to protect New Zealanders involved in clinical trials. Thus there is no requirement for objectivity or impartiality when the safety of participants is being weighed against the objectives of the study.

Charging participants

**Please outline your reasons:**

We are unsure. Any proposal to charge participants should be highly scrutinised.

**Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Big data and new ways of using data

Agree

**Please provide feedback:**

**Databanks**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Human tissue**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Biobanks**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

We believe that tissue should be made available for future research purposes.

### **Research with stem cells**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Response number	25
Name	[redacted]
Organisation	[redacted]
Role	Senior Lecturer
Interest group	Academic
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

**Please outline your reasons:**

The standards are applicable to all types of health and disability research  
Agree

**Please outline your reasons:**

The standards balance protecting individuals with the realities of conducting research  
Agree

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research  
Agree

**Please outline your reasons:**

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Strongly Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:**  
Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Strongly Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**  
Strongly Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Strongly Agree

**Standards - protect and reassure the community:**

Strongly Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

1.2 strong focus on individualistic nature of health care and health outcomes. Those from collectivist communities put emphasis on self-determination and the health and wellbeing of the community. World Health Organization health goals might be relevant to include: Inclusion and participation.

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Neutral

**Please provide feedback with reference to the paragraph(s) in question. :**

6.3 and 6.4 the term 'cultural rigour' is used but what does this mean? this has not been defined

### **Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

In section 10.12 have potential cultural harms been considered ? such as harm to wairua or to mana.

### **Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

11.5 should these be aligned with the 13 characteristics specified in the Human Rights Act

11.5 sexual orientation is not specified and should be included.

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Response number	26
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable

Agree

#### Please outline your reasons:

Given that the standards are for research, they are fit for that purpose. However, we would like to see a section which covers new ways of using data, such as for predictive algorithm development and use in clinical practice. The feedback section mentions 'big data' but the body of the standards does not.

The standards are applicable to all types of health and disability research

Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research

Strongly Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research

Agree

#### Please outline your reasons:

Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:**

Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Strongly Agree



**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Strongly Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:** Neutral

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Neutral

**Please describe the ethical challenges that are missing:**

New data uses are not covered by these standards, such as using routinely collected data to develop predictive algorithms (e.g. predicting health outcomes following a health event). Section 4.6 broadly covers such use by saying that 'people involved in activities that share features of research should follow these standards'. We agree that the standards provide a useful framework for development of algorithms, especially the 'data harms' section. However, it is not possible to follow consent rules in the standards for this development. It would be good to have greater clarity around what is meant by 'should follow these standards' and perhaps specific recommendations regarding consent for this purpose.

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

The scope is clear and includes research only. Please refer to earlier comments about expanding the scope of the standards to include new ways of using data, especially predictive modelling using routinely collected (existing) health data. These uses, by nature, involve linking across disparate datasets. The standards specifically require consent for such data linkages. Expanding these standards to give more specific guidance to predictive data modelling would be appreciated.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

4.19. We suggest you add a condition of:

'the innovative practice may broaden health inequities'

Response number 28

Name	[redacted]
Organisation	[redacted]
Role	Community member
Interest group	Consumer
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

**Please outline your reasons:**

The standards are applicable to all types of health and disability research  
Agree

**Please outline your reasons:**

The standards balance protecting individuals with the realities of conducting research  
Agree

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research  
Agree

**Please outline your reasons:**

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Neutral

**Standards - reflect the principles of the Treaty of Waitangi:**  
Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Neutral

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**  
Neutral

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Neutral

**Standards - protect and reassure the community:**

Disagree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Neutral

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Human tissue**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

My comments are specific to the sections on genetics. It is essential to keep this section up to date in a rapidly changing and ethically challenging technological world. It is unclear in this section whether New Zealand law includes similar legislation to GINA in the US or S-201 in Canada, preventing genetic-based discrimination in such areas as health insurance and employment. <https://www.genome.gov/10002077/>

This should be clarified - based on current wording eg in 15.35 and 15.39, it seems no such legislation exists in NZ. If that is the case, should NEAC be addressing this with legal authorities? This will have a major impact on genetically-based studies and appropriate dissemination of such information, if participants are not legally protected, although such legislation is admittedly prone to loopholes.

In section 15.39, bullet 5, it is stated that researchers provide access to genetic counselling OR recommend that ppts seek these services. It is my understanding that these services are only provided free to individuals meeting certain criteria. If that is the case, then ppts may be disadvantaged financially, or may choose not to have counselling due to cost. In these instances, the research plan should cover these costs, both for ethical and research adequacy reasons.

The section on gene editing gives a nod to this important new development, but I suggest it should be stated more clearly that ethical issues surrounding these and upcoming technologies will be monitored and updated as required. <https://www.genome.gov/27569222/genome-editing/>

Lastly, I may have missed this, but it seems strange not to mention pharmacogenomics in a section on genetics, unless it is unlikely that NZ researchers will ever participate in this field.

Response number	29
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable

Agree

**Please outline your reasons:**

The standards are applicable to all types of health and disability research

Agree

**Please outline your reasons:**

The standards balance protecting individuals with the realities of conducting research

Agree

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research

Agree

**Please outline your reasons:**

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Biobanks**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

The problem we have come across is that people see a biobank as a freezer, ie you have a biobank, and I want to biobank these samples, so if I put them in your freezer then I'm covered. MANY researchers still think this way. I think this needs to make clearer that a biobank is not just a collection of samples, but a framework of use that governs a set of samples. I think the protection of a biobank is that it links researchers into a collective that provides better structural protections for participants, rather than single researchers doing their own thing. It also provides protection of samples into the future where individual researchers may leave but the governance still applies.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Response number	30
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

The document is structured in a manner that is easy to follow, is practical and describes processes and guidelines in an accessible manner

The standards are applicable to all types of health and disability research  
Disagree

#### Please outline your reasons:

There is no mention of research with LGBTIQ+ populations, apart from the reference to diversity in gender and sexuality as a marker of vulnerability. It would be good to include particular considerations when conducting research with this population, even though there are some overlap with Maori and Pasifika populations

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Disagree

#### Please outline your reasons:

The standards do support researchers to navigate some ethical challenges, but the omission of a discussion on research with LGBTIQ+ population fails in this regard

### Overall do the Standards?

#### Standards - safeguard the rights and interests of participants in research:

Neutral

#### Standards - promote high-quality ethical research for social, cultural and economic wellbeing:

Agree



**Standards - reflect the principles of the Treaty of Waitangi:**

Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Neutral

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Disagree

**Standards - protect and reassure the community:**

Disagree

### **Coverage of ethical guidance**

**The standards adequately cover the ethical challenges that are present in health and disability research**

Disagree

**Please describe the ethical challenges that are missing:**

There are considerable challenges in doing research with LGBTIQ+populations and given the fact that individuals in this group are over represented in the suicide statistics in NZ there should be clearer guidelines on how to consider the ethical challenges inherent in conducting research with this population

### **Merging the observational and interventional guidelines**

**The standards are applicable to both observational and interventional research**

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

I would suggest including sex as a diverse category alongside gender and sexuality

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

8.12 - include sex, alongside sexuality and gender

### Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

Under standard 11, considering cross-cultural research, including LGBTIQ+ populations, it is important that the principal researcher consults a person with appropriate knowledge, skills and experience throughout the research process rather than the proposal being reviewed once.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

11.7 could be revised to include ongoing consultation rather than reviewing as an adequate process to ensure the integrity of cross cultural research

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

13.75

The ethical issue of deficit thinking and victim blaming also strongly applies to the LGBTIQ population given the medical profession's pathologising of sex, sexuality and gender diversity. The wording of this issue should include reference to this population.

### **Charging participants**

**Please outline your reasons:**

Yes it is helpful to discourage researchers to charge participants for participating.

Response number	31
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable

Strongly Agree

#### Please outline your reasons:

I was really pleased with the new standards. They contain what I was expecting (always a relief).

The standards are applicable to all types of health and disability research

Strongly Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research

Strongly Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research

Agree

#### Please outline your reasons:

Yes, very helpful.

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Strongly Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Strongly Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Strongly Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Strongly Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Strongly Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Strongly Agree

**Please describe the ethical challenges that are missing:**

I can't find the place to comment on Section 3 Users' guide to these standards so I'm putting my comments here.

3.7 - for clarity, maybe you can include specifically HRC accredited IECs as being among the review bodies over which the NEAC and their standards have precedence. From the perspective of the IEC, it will make it much easier to enforce the standards if we can point to the wording and say to researchers 'look, this is the place where it says that you must comply to these standards'. The current wording 'a review body' leaves room for a little bit of ambiguity.

3.15 - and here for clarity include HDECs and HRC accredited IECs.

Should versus must

'must' has a circular definition. How about this wording?

'must' means that compliance with a standard is required; any exceptions to the standard are clearly detailed.

'should' indicates that compliance with a standard is a matter of good practice and is recommended.

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

Nice work here, and good if it picks up activities happening outside those traditionally understood to be observational 'research' and interventional 'research'.

### **Scope of the standards and non-research activities**

Is the scope of the document clear?

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

I really liked the wording of 5.2, and also Figure 1.

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

In spite of the attempt to be inclusive by using the phrasing Polynesia, Micronesia and Melanesia, this section is very 'Polynesian' in the commentary section. There is a risk of alienating Pacific people who do not recognise the wording. Rather than omitting it, I think you could maybe acknowledge the source language of indigenous terminology (fonofale, alofa, ava etc. - do these terms all derive from the same language, and which one?) and to indicate that the terminology serves to illustrate one set of Pacific values, rather than to imply that all Pacific people share the same values. Beliefs about and interactions with the human body after death are vastly different, for example, in different parts of the Pacific.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

How much HRC funded research relates to Micronesia and Melanesia? Is this section trying to be more inclusive than it needs to be? Or are NZ interests in the Polynesian Pacific?

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:** Wording suggestion for 7.2: an holistic (rather than a holistic)

### Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

There is a lot of very clear and helpful information in the commentary.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

I wondered about signalling language difference as a factor somewhere. It needn't be a vulnerability, but perhaps a separate subsection.

Statements could be including about the requirement to provide an interpreter for participants whose main language is NZSL, and links to resources that support the preparation of written materials for NZSL users. This is a 'must' in my view.

Likewise, an overt statement about the importance of providing documentation in te Reo, and providing opportunities for participants to communicate in te Reo if that is their preferred language. This might be more project-specific - a 'should'? I see this is picked up on in 9.19.

A final point could perhaps be something about the needs of non-English speaking participants (participants shouldn't be excluded because their English isn't very good - how can researchers better support their participation?) This could be an opportunity to introduce/reinforce the need to use clear English in project documentation for participants.

Along the same lines, I'm assuming there will be a version of these Standards translated into te Reo and made available at the same time as the English language version is released? And maybe some online video resources in NZSL too?

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Wording suggestions: rather than 'research in', how about 'research with'? (Research in children and young people, Research in women - yikes).

## Informed consent

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

I found this section problematic, as the NEAC is advocating for a practice which is actually illegal. This seems like poor form (although I understand the rationale) and I think you should wait on the law change before distinguishing between minimal risk research and more than minimal risk.

Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

I found the information in this section to be very useful.

## Research benefits and harms

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

See below

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**



10.12 - I like the inclusion of Table 2, and particularly the inclusion of 'cultural' in the section on 'Social or cultural harm'. I'd like to see cultural harm expanded on (the current focus is pretty much 'social'). Some acknowledgement that there are cultural belief systems and practices which differ vastly from western medical values and practices would be good here, especially as there is a bit of a history of dismissing values and practices which fall outside of the institution.

### Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Protocol

11.11 - after a fantastic start leading with principles from Te Ara Tika, no mention is made of a description of consultation undertaken, and how feedback has been incorporated into research design. And the all important partnership arrangements fall second to last on the list. These could sit around bullet point 6. Just saying...

### Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

14.43 Table 6 Cultural Harm has fallen off, and I think should be included here, given the potential for generalisations to be made from data about groups of people.

Big data and new ways of using data

Not Answered

**Please provide feedback:**

Response number

32

Name	[redacted]
Organisation	[redacted]
Role	Research Manager
Interest group	Researcher
Publish response	You may publish this submission

## Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Strongly Disagree

### Please outline your reasons:

General concerns about the Standards are as follows.

- A clear definition of what a Standard is, what it means in practice and how it can be measured or applied is lacking. For example, in 3.21 it states that 'should' and 'must' are similar but 'must' is stronger. It states that 'must' means the standard is the minimal standard that must be met, but the status of the 'should' statements is unclear. We suggest providing a clearer explanation and examples of how 'should' statements are to be applied and interpreted in practice.
- Some of the Standards are poorly written, ambiguous and lack a clear purpose. Specific examples are given in later sections. All of the Standards must be written in such a way so there is no confusion about how they can be measured and put into practice. It should be clear to the researcher, ethics committee, participants and others how the Standard can be met. It should also be clear what the point of the Standard is, what action is required to achieve it and why this is important.
- Not all of the 'Standards' include a 'must' or 'should' statement (eg, 8.8, 9.9, 9.77, 9.79, 12.3, 13.2, 13.3, 14.22, 14.32, 17.14, 17.26). We suggest all of the 'Standards' be framed as a must or should statement, to improve consistency, comprehension and clarity of the Standards. Any 'may be' statements should be discussed in the commentary but not be included as Standards.
- There are many cases where there are should or must statements in the commentary but these are not included in the listed 'Standards'. This is confusing and the status of these additional must/should statements is not clear. 3.2 states that each chapter contains standards that researcher must meet, 3.3 says the commentaries provide guidance on how to apply and interpret the standards, but there is no guidance on how important the commentaries are. We suggest careful consideration of all the should/must statements in the commentaries and assessment about whether these should be 'Standards' and if not, then revising the language to mitigate this ambiguity and/or explanation provided as to how and why they are different and distinguishable from the Standards. We highlight specific examples in later individual sections. In general, we suggest that any statements in the discussion that have strong 'should' or 'must' recommendations are considered for inclusion as specific Standards, unless there is a compelling reason not to. This would make the Standards clearer and more comprehensive and ensure that important areas of action are not missed by researchers, who may primarily refer to the Standards and not always read the commentaries in detail.

- The commentary often does not clearly relate to or support the Standards; they are often repetitive and create ambiguity rather than clarity. We highlight specific examples in later individual sections. The commentary sections are also often lengthy and poorly constructed, so the information in each section does not clearly relate to the headings and it is difficult to find relevant details. To greatly improve the clarity, helpfulness and workability of the document, we suggest that each Standard has its own commentary, so it is explicit what commentary pertains to what Standard. This would also mean the commentaries are limited to areas of contention, further detail, exceptions/special cases and hazy areas where a should/must statement is not appropriate, which would make these sections much more relevant. The commentaries should explain how the Standard can be met, and how all involved will know that the Standard has been met, if the Standard is not able to be explicit about this or involves some caveats.
- Related to the issue of the commentaries, it is not clear why some information appears in the introductory section and other information is in the commentary. There are instances where useful introductory information is missing or is located in the commentary. The document would be greatly improved if the introductions contained all the useful background information, definitions and context for the Standards, with the commentary related much more clearly to specific Standards, and elaborating more on these as required. Specific examples are provided in individual sections.
- There is significant overlap between sections/chapters and insufficient cross-referencing. Specific examples are provided in individual sections. A major example of this is Ch 14, which contains Standards related to research with Māori, informed consent, harms and benefits, privacy and confidentiality, research conduct, with no cross referencing or harmonising with other sections.
- The order of the contents does not make sense and some of the section headers are inconsistent or inappropriate for the content of the sections. For example, it is not intuitive that informed consent is considered before Research development and design. Types of studies would make sense to appear earlier in the contents. The title of 'Types of studies', 'Categories of participants' and 'Health Data' doesn't reflect well the content of this chapter. Research benefits and harms would sit better before the chapter on Research involving Maori, as this sets up the discussion on 'benefits'. Other specific examples are provided in individual sections.
- A summary that lists all the Standards in one place (with links to the more detailed context and commentaries) would be helpful.
- A glossary and definition of terms would be helpful.
- The presentation about the Standards given at the Wellington consultation meeting articulated some aspects more clearly than is currently done in the document eg, there was a clearer explanation and discussion of proportionality of ethical review (which must also be applied to research that does not get formal ethics committee review) and scope of applicability of the Standards to "research" in its various definitions. Suggest that the content of this presentation is considered alongside the current draft guidelines and included where the guidelines are lacking in this context and detail.

### The standards are applicable to all types of health and disability research

Disagree

#### **Please outline your reasons:**

The Standards and associated commentary do not always make clear where the Standards apply to different types of health and disability research. This needs more work, to make the guidelines more effective and usable. Some specific examples are given in the feedback on individual sections.

That the standards apply to all health and disability research and related activities, regardless of whether the research is reviewed by an ethics committee, deserves consistent emphasis. Hence,

the first sentence of 1.3 should be reworded to be consistent with a very similar sentence in 4.1 (the 1.3 sentence is overly wordy).

The standards balance protecting individuals with the realities of conducting research

Disagree

**Please outline your reasons:**

The realities of conducting research do not appear to have been appropriately considered in some sections. See later comments, eg, Research with Māori.

The standards support researchers to navigate ethical challenges in health research

Disagree

**Please outline your reasons:**

We have concerns about the practical navigation of the guidelines. The document is very long, unwieldy and it is not clear how this will be usefully translated to an online version. The underlined blue words which go to further information, are not always helpful and there are many areas where links would be helpful but these are missing. We suggest undertaking a robust process to ensure the online version of the guidelines are adequately tested before release, including assessment of whether they are easy to access, easy to navigate, readable and usable on different types of browsers and devices and that all the links work and go to the right information. This includes considering and communicating how the document be made web-friendly and searchable, how it will be kept up to date and how will users be notified about revisions in the future, how sections will be linked effectively and consistently, how the important, need to know information will be highlighted. We recommend that there is an additional round of targeted consultation of the online version to ensure this version is fit for purpose.

We also strongly recommend a thorough edit of this document, particularly to eliminate repetitiveness and duplication (some specific examples are provided in later sections). Many sections contain information that is relevant to other sections but it is not clear how these will be linked.

NOTE - We were unable to rate the 7 statements below about 'Overall do the standards...' A neutral response has been given only because a response was required to complete the submission.

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:**

Neutral

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Neutral

**Standards - reflect the principles of the Treaty of Waitangi:**

Neutral

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Neutral

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Neutral

**Standards - help researchers give due consideration to local and national community views and perspectives:** Neutral

**Standards - protect and reassure the community:**

Neutral

### Coverage of ethical guidance

The standards adequately cover the ethical challenges that are present in health and disability research

Neutral

**Please describe the ethical challenges that are missing:**

The Standards raise the issue of how ethical principles can sometimes be in conflict (5.11) but do not offer much guidance about what to do in these cases. The example given in 5.11 is difficult to understand and offers no clear solution or approach to deal with the conflict.

There is insufficient clear guidance on what researchers must do when undertaking research on linked data that is not identifiable. This is an important issue, as many researchers working outside university institutes access linked datasets eg, in the IDI, and have no access to an ethics committee to review research proposals. We need clear direction on this, as the HRC has indicated that use of secondary datasets such as the IDI may/should have ethics committee review. We do not agree with this advice as the risks of harm are very low and can be managed in the same way as other minimal risk research. It is also unclear how this relates to current processes of review of IDI data projects. This advice would create a great deal of difficulty for researchers, and almost certainly hinder or prevent useful research from progressing, and provide no additional protection to research participants, whose data are de-identified. It is not clear that the advice in 14.56 applies to data such as the IDI which has already been linked.

### Merging the observational and interventional guidelines

The standards are applicable to both observational and interventional research

Neutral

**Please outline your reasons:**

Merging the guidelines is a positive step. As noted elsewhere, there are places in the current draft where it is not clear which Standards apply only to interventional research.

### Scope of the standards and non-research activities

**Is the scope of the document clear?**

Disagree

**Please outline your reasons or suggested improvements:**

The document is large and complex, and there is a lot of repetition. Smaller providers or community groups wishing to understand the needs of their community, for example, would be significantly disadvantaged by this.

Paragraphs 1.5 and 1.6 could be re-worded to be clearer and easier to understand – they also need to either link to 3.8 or incorporate the information in 3.8. This is because paragraphs 1.5 and 1.6 raise questions (eg, what are the other guidance and codes of practice, and who decides what are minimum standards/what is inconsistent), which are partially answered in 3.8. It seems like the practical point is that where there are gaps in the NEAC guidelines it is prudent to consult other guidance (this is a better alternative than researchers doing whatever they want to).

Also note that 3.8 is in a section titled 'Complying with NZ legislation' but this is inconsistent with the text in this section, which mentions international conventions in the last sentence of 3.8 and international conventions in 3.9. The heading 'How the standards apply to NZ legislation' is also inconsistent with the text below, which is not about this at all.

1.5 says 'researchers must refer to [other guidance].' We suggest clarifying whether this is a Standard or not and how it would be measured/ complied with.

1.6 is repetitive – have already told researchers they must refer to other guidance in 1.5. The first sentence is long and difficult to read – suggest revising so it is simpler and clearer.

4.3 the box is a broad description of health and disability research (similarly, 4.4 should refer to a definition of 'health and disability research' not merely

'research'.) This creates some ambiguity about whether the guidelines apply only to health and disability research or a broader range of research (including social science research). This needs to be clearly resolved. If the scope of the document is to include non-health research, the implications of this need to be clearly spelt out and discussed, especially the implications for social science researchers.

4.5 It is not clear what is meant by 'all practices where they are relevant'. Please explain.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

The Introduction needs to be distinguished somehow from the Introduction to the Standards, if it is intended to be included in the final online version. In the Introduction, it states 'In order to review the 2012 guidelines and develop new standards determined by NEAC, the Ministry of Health established a Working Party to create a first draft.' This seems to be misleading, as the Working Party started at the end of 2017, whereas the review had begun in 2015.

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

This section contains some poorly defined ideas and concepts that have the potential to lead to confusion. Examples include:

- 6.3 and 6.4 Cultural rigour is something the Standards say that researchers must demonstrate, but no definition is provided and there is no discussion on what this means in practice or what the implications are. We might infer that cultural rigour means researchers have to consult in a certain way, share benefits with participants, but this is not explicitly stated. Some guidance also needs to be included on how researchers will know they have met this standard and how to assess the cultural rigor of research or researchers. 6.4 is closer to a useful standard than 6.3, which is too weak and needs a tighter definition.
- 6.5. The Standard around researchers acting with integrity and transparency should apply to all research. Suggest making this a Standard that applies generally (with appropriate re-inforcement that this is especially important in research with Māori). Also suggest that the second sentence become a separate Standard that is specifically relevant for research involving Māori. Also, 6.5 would be much clearer and easier to understand on a first reading if it used the same language as the commentary. There is an apparent inconsistency with 6.12 which says early consultation is preferred whereas 6.5 says consultation should form part of gaining agreement for the proposal. This creates the perception that 'should' statements are to be interpreted as a 'preferred option' (ie, do it if you want to but no obligation to adhere to these) which may or may not be intended. This relates back to the previous comment about needing to more clearly define the status and interpretation of 'should' statements.
- 6.6 This standard is unclear. It seems like an 'and' or 'so what' is missing. It seems a very low bar to include as a standard - you could meet this by identifying the appropriate group and then doing nothing to ensure the engagement with the research is appropriate, for example. Different populations will signal different approaches and ethical standards (e.g. Māori iwi leaders vs young Māori mothers living in economically disadvantaged communities). Sometimes the Māori population may be identified after consultation with a Māori stakeholder grouping or the Māori stakeholders may be the research population. Perhaps change to and/or to keep some flexibility, but add something like "... researchers must clearly state the criteria used in identifying Māori who are to be part of the research and make that clear in the all research documents, including to all research participants"
- 6.7 "Researchers must collect ethnic data (allowing multiple ethnic identifications), unless there is a valid justification why that is not necessary" An explanation for this could be to ensure parity with contemporary understandings of ethnicity and with Stats NZ ethnic data standards.
- 6.9 Needs to acknowledge the cumulative effects on health and wellbeing of the loss of the Māori economic base due to colonisation and on-going discrimination.
- Box 1 (and these comments also apply to the section as a whole) – The expectations regarding Research involving Māori are not sufficiently clear or well defined. For example, 'iwi research' is referenced in the box but there is no definition of what 'iwi research' is. Also what is a 'collectivises' – is this a typo for 'collectives'? Need to explain what is a 'collective' and what defines 'involved'. Some discussion is also needed about how researchers/ethics committees can confirm that a research design, method and analysis is appropriate for Māori collectives and how this is different from being appropriate for Māori individuals. A specific application of this that needs further clarification is what this means for research that asks about iwi affiliation as part of gathering information about individuals but is not researching specific iwi ( a common occurrence in survey work). It is currently unclear whether this means that any research that involves Māori who have an iwi affiliation (regardless of whether this is asked about in the research) must consult with a collective body. If this is required, some guidance about how, who and why this consultation is undertaken would be helpful (eg, do the iwi governance groups want/need to be consulted on every research proposal that includes a Māori individual with an iwi affiliation?) This is really important to be clear about – ambiguity here will create many potentially serious unintended consequences. If the expectation is that any research with any 'collective' content (eg, iwi affiliation) requires a collective consent from any/all potentially interested iwi groups at the proposal stage (which the document as it stands could imply) then this would almost certainly



result in this type of information not being asked at all. Another question to be answered is how does this Standard apply to existing or ongoing research that collects iwi data.

- Box 1 – this assumes that all research will have institutional review, which is clearly not the case. This needs to be made applicable and relevant to all ‘types’ of studies and health and disability research.
- Sharing benefits with Māori – we need some more information about what constitutes a ‘benefit’ (eg, links to 10.90 and Table 1).
- 6.22 ‘Researchers must be honest and open about all parts of their research etc...’ This doesn’t seem to belong here. It is of general relevance and has no apparent exclusive relevance to research involving Māori. Also another ‘must’ statement that could be turned into a Standard. Also, some definition of what ‘honest and open’ means would be helpful.

The section is also poorly constructed and difficult to follow, meaning that readers would find it hard to find the information that is important and relevant to them.

Statements that include ‘should’ are included in the commentary and it is not clear whether these should be Standards. Examples include:

- The introduction section needs to introduce the different types of research involving Māori (as in Box 1), as these are potentially crucial distinctions.
- The entire commentary section is repetitive and would benefit from a good edit, especially the consultation sections. The three headings of Engaging and consulting early, Consultation and Degrees of Consultation are confusing. 6.17 and 6.18 in the section ‘Consultation’ appears to be a justification/explanation of why we should consult and perhaps would sit better in the introduction.
- The section ‘The importance of health research with Māori doesn’t clearly relate to any particular Standard. 6.8 is repetitive of the content in 2.8. 6.9 would fit better in the introduction. 6.10 introduces health inequities as an argument ‘supporting a focus on Māori health aspirations in the ethical review of all health research’ but does not explain what this means in practice.
- The second sentence of 6.11 could be a standard. (eg, Every study in NZ should consider the degree to which it can contribution to improving Māori health outcomes. [bolded addition to make the sentence clearer]).
- The first sentence of 6.11 is of general relevance to this whole section and is not just about engaging and consulting early. It would fit better in the introduction section or as a comment on the second sentence of 6.11 (if this is made a Standard). 6.12 doesn’t relate clearly to any Standard.
- 6.13 could be a commentary on 6.11 (also doesn’t relate to any Standard) but does not really fit in a section on consulting early. It is more about research development.
- 6.14 Two ‘should’ statements in here: ‘Māori participation in research is important and researchers should facilitate it’ and ‘Researchers should develop relationships with Māori that are effective, appropriate and meaningful, with an equal balance of power’. These could be Standards but would need some discussion on how they would be measured.
- 6.14 ‘A process of consultation with Māori will be inadequate if those consulted play no part in framing the research question or if their opinions are not reflected in the analysis and research outcome.’ It is not clear what type of research this applies to. This and the final sentence of 6.14 are not clearly related to a Standard. (This is a good example of how having the Standard with the relevant commentary immediately associated with it would improve the clarity of the document.)
- 6.15 Contains must statements – not clear whether these are similar status to the Standards.
- 6.15 states that researchers must give Māori adequate opportunity and resources to engage in the research. Suggest that this should apply to other research participants also.
- 6.18 Need some explanation of what are the conceptual issues and questions that researchers need to consider. It is not clear how 6.18 relates to ‘Consultation’ or the Standards. Similarly, the shape of research outputs is vague. It would be useful to state that the language and level of

detail used in disseminating research outputs must match the requirements of the end-users of the research outputs.

- 6.19 It is not clear why this is included here. It also does not relate to 'Consultation' or any Standard and is of general importance and could be easily overlooked/missed.
- Box 1 – heading 'different types of research' could be confusing. Chapter 12 talks about 'types of studies' with respect to observational and intervention studies but the 'types' of research here are those with different levels of engagement with Māori.
- 6.21 contains a 'should' statement but it is not really clear what this means ('researchers...should consider the potential benefits for Māori participants..') Similar to 6.6, it looks like a 'so what?' is missing, since 'considering' doesn't necessarily translate to any action. Suggest including a relevant action to explain the purpose/intent of this statement. Consider changing "should also" to "must".
- 6.22 contains 'should/must' statements. For the 'should' statements, again, it would be clearer if these recommendations related more clearly to an outcome.

Suggest being explicit about what is expected after reviewing prevalence and health outcomes eg, relate this review clearly to the research objectives, methods etc.

- 6.22 Requiring researchers to declare how they will personally benefit seems impractical if not ridiculous and obscures the main requirement about declaring conflicts of interest. It is not apparent how this will provide any useful information other than researchers routinely stating something like 'This will help me do my job and improve my chances of progressing in my research career, which may improve my income'.
- 6.23 'the protocol should...' could be considered for whether it should be a standard. However, we have reservations about including this as a standard. For example, it is common for surveys to over-sample Māori and to sometimes recruit a higher proportion of Māori in the final sample than is in the total population and it is not clear whether this is what is meant by a 'higher proportion' – or whether this means 'more than 50%' (or something else). Some clear interpretation of what a 'higher proportion' means is required. Many surveys (eg, the New Zealand Health Survey) are undertaken for monitoring and surveillance and it is not clear how these will demonstrate a greater benefit for Māori. These types of surveys benefit the entire population but not necessarily one group more than another. Some explanation of the expectations for how benefits can be greater for Māori than other groups with respect to observational research/surveys would be useful. Table 1 (not Table 2) lists potential benefits for participants, but only 'koha' could be differentially applied to one group over another. The conclusion from this is that Māori participants should be given a larger koha for participation in research if Māori are over-sampled – if this is the case, it would be helpful to state this explicitly and provide a justification for this. Other benefits listed in Table 1 also cannot be easily applied differentially/increased for Māori, so they have more benefits. The examples of 'benefits' (in the second sentence of 6.23) such as ensuring participation, involving Māori in interpreting results and providing feedback does not look to be providing greater benefit for Māori, seem to be aspects of best practice that should be included in the standards, and apply to all participants, rather than examples of 'benefits' that could be applied in a greater measure to Māori. These examples given could be read to imply that research should benefit Māori by consulting and providing feedback to Māori but not other participants, because doing this would provide a greater benefit to Māori. Please provide a better explanation of what is meant by providing a greater benefit and give some examples of how this could work in practice (alternatively, revise this section entirely).
- 6.24 – the 'must' statement here is better wording for the Standard 6.7. (A good example of the repetitiveness in the document and how the Standards and commentary need to be more closely aligned.)
- 6.27 this belongs with 6.24 and is somewhat repetitive.

Editorial notes:

- Please be consistent with use of macrons – there is not always a macron on the ‘■’ in Māori in the document.
- 6.1 includes a quote with no reference.

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Strongly Disagree

**Please provide feedback with reference to the paragraph(s) in question. :**

See response above.

### Research involving Pacific peoples

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

Similar comments apply to this section as to the section on Research involving Māori, including that it would be much clearer if each Standard was immediately followed by the commentary/ interpretation/ application relevant to that Standard. There is the same issue of ‘should’ and ‘must’ statements in the commentary.

Specific comments:

- 7.5 introduces the idea of ‘cultural integrity’ but it is only in 7.18 that an attempt at defining this is made. It is not clear how cultural identity compares to the ‘culture rigor’ introduced in 6.4 and 6.4. Suggest these concepts are harmonised, to improve comprehension, consistency and simplicity.
- 7.7 There seems to be a ‘so what’ part missing from this – some guidance about what researchers are expected to do after they aim to understand Pacific dimensions of health would be helpful. This seems inconsistent with the commentary in 7.11 where researchers are ‘encouraged’ to build their knowledge. Having this as a ‘should’ statement implies it can be ignored.
- 7.8 This is a good example of how the Standard would be more understandable if it was clearly and immediately linked to the commentary about it.
- 7.9 would belong better in the introduction.
- 7.12 doesn’t clearly relate to any standard. It also seems inconsistent “researchers are encouraged to involve a Pacific researcher etc” with 7.13, which states that “for research that involves a community, researchers should consult...”
- 7.12 and 7.13, when read together, are confusing. It needs to be clearer as to what kind of research these statements apply to. 7.13 contains a should and must statement which are additional to the Standards.

- The purpose of the commentary in 7.15 is unclear. The meaning of 'researchers should take account of this relationship ..' is not clear. Also contains 'should' statements (it is unclear whether these are 'Standards')
- 7.16 Not clear what Standard this comment relates to. That researchers 'are encouraged to' is weak, suggest strengthening this.
- 7.17 contains should statements about consultation but the Standards themselves do not specifically mention consultation or engagement despite 7.4 saying that the standards focus on the consultation process. 7.5 refers to 'established meaningful relationships' which may refer to consultation. Please make the Standards about consultation and engagement clearer.
- 7.18 should statements here might be more appropriate as Standards. However, it needs to be made more explicit in all the Standards as to what kind of research these apply to. It might be helpful to distinguish different levels of research engagement according to the potential impact and involvement of Pacific peoples, as for the Māori research section.
- It would be helpful to consider the Standards for Research involving Māori and those in this section together, and make the language consistent across both sections and highlight similarities and differences, where these occur.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

A standard around the collection of ethnicity of Pacific peoples should be included. See also response above.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

### Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

The title of this section 'Categories of participants' does not fit well with the content, which discusses 'vulnerable participants'.

Feedback about the Standards:

- 8.1 – 'Researchers must...' It doesn't seem appropriate to start the introduction with a 'must/should' statement that looks like a Standard.
- 8.2 would read better/be clearer if premised by something like 'When research in vulnerable individuals is undertaken...'
- 8.5 is vague and 'specifically considered protection' is not explained. Another example of how the commentary should be directly linked to and adequately explain the Standard.

- 8.6 should apply to all participants, not only vulnerable participants (ie, belongs in the section on informed consent). Some guidance needed on what is a 'reasonable' decision and how this would be evaluated.
- 8.8 doesn't include a should or must statement and no guidance on how this is to be applied.
- 8.9 is obscure when divorced from the commentary and explanation of an unequal relationship.

Feedback about the commentary:

- 8.12 would fit better in the introduction. The 8th bullet point doesn't fit – needs to be phrased like 'people with vulnerability..' Appears to be duplicative by having a bullet point for people with vulnerability related to age and also 'some older people'
- 8.13 contains must/should statements.
- 8.14 also contains must statements and needlessly repeats 8.5 (although the wording for this is better in 8.14 – suggest replacing the Standard with this type of wording, which makes it clearer what the Researchers are responsible for).
- 8.14 example of where a conflict of principles is raised but no guidance is provided for how to resolve this conflict.
- Capacity to consent section is not discussed in the informed consent section (Ch 9). These should be cross referenced in some way. This section also contains many must/should statements.
- 8.18 Some clarity needed about how potential conflicts of interest in supporters would be evaluated.
- 8.21 'Declining to participate... should not result in any negative consequence' – this should be stronger than a 'should' statement – they **MUST** not.
- 8.22 and 8.23 Interesting context, but not clear what the purpose/action is. The headings here (for 8.20-8.25) are not ideally matched with the content.
- 8.24-and on – more must and should statements (too many to list in full).
- Another conflict highlighted in 8.24 – balancing the burden of participation with potential benefit, but no guidance given on how this could be assessed and resolved.
- 8.25 first sentence already said in 8.9 – repetitive. Second sentence a great example of providing some useful guidance on how to apply the Standard – more like this is needed.
- 8.28- 'if a child is under 16 years old and lacks the necessary capacity to give legally effective consent, the researcher gets consent for the child to participate from their parent or legal guardian.' There is insufficient information given here about what defines 'legally effective consent' and how this is assessed. Not appropriate to apply this to children under 16 years - this is inconsistent with current practice in research companies eg, Article 8 of the RANZ Code states "The informed consent of the parent or responsible adult shall in all cases first be obtained before interviewing children aged under 14 years of age. In the case of studies containing sensitive subject matter, e.g. mature or controversial themes, parental consent shall also be obtained for children aged 14 and 15." Need to provide some justification for the 16 year threshold and why this is different to current practice. The implications of this is significant and may mean that research with 14-15 year olds is reduced, because of a potential or perceived requirement to get consent from parents.
- 8.30. Repeats some content from 8.28.
- 8.32 repeats what is said in 8.28.
- 8.35 is of general concern – should be a Standard that applies to all participants.
- 8.36 This statement says the researcher 'needs to' do something but it is not clear whether this is equivalent to a 'must' statement. Please clarify this (here and in all other places where this terminology is used).
- 8.37 repeats 8.11.

- 8.39 There might be exceptions to the statement 'The wellbeing and care of the woman who is pregnant or breastfeeding and or her fetus or baby always takes precedence over research considerations' [bold added], depending on how 'wellbeing' is defined.
- 8.40 This appears to exclude the woman from the decision to continue to participate. She should have a say, with fully informed consent, in this decision.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

There does not seem to be any mention of how vulnerable participants would be offered support and protection if the research results in or increases the risk of harm for these individuals. For example, research in people with mental health conditions could exacerbate thoughts of suicide; research on family violence could exacerbate risks to the wellbeing of partners and children (eg, if an abusive partner discovers the participant has disclosed abuse to the researchers). There is an ethical obligation on researchers to consider these risks and take active steps to effectively mitigate them. This is discussed in section 10, at some level, but it also needs to be discussed in this context – or appropriate reference made to section 10, and appropriately specific content included in section 10. Also comment in 14.47 that would be relevant here. This is another example of how information is scattered throughout the document in a way that a researcher will not be able to find all the guidance on a particular topic that is needed.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

**Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

Overall, this chapter is long and difficult to navigate. Condensing this section would go a long way to making it more useful. The Standards are split into two sections which is confusing. This section would particularly benefit from a review of its structure and readability and consideration of which aspects apply generally to all types of research and which apply only to some types of research, and clearly distinguish these so the application and context for each Standard is obvious. It also contains many should/must statements in the commentary, which we have not listed, but these need to be evaluated for whether they are included as 'Standards' or not.

9.3 appears to have relevance for section 6 and should be cross referenced.

9.10 should be the first Standard in this section – all the others come after this.

9.7 it is not clear that this is not relevant for all types of research eg, data linkage studies. 9.8 It is not clear what is meant by 'View participant information sheet requirements'

9.9 It is not explained why modifications require ethics committee approval. There is no mention that informed consent per se requires ethics committee approval.

There are certain types of research where no ethics committee approval is required, so this should not be a Standard.

9.16 This doesn't apply to all types of research. A definition of 'study processes' is needed.

9.17 Recognition is not sufficient – access to support is a requirement.

9.19 Guidance is needed here as to what to do to mitigate this risk effectively.

9.24 'Retribution' sounds vengeful – 'consequence' would be more appropriate. See 8.21 and 9.27

9.34 could be seen as in conflict with 9.31. It also has an inherent conflict, stating researchers 'must' provide this information, but with the caveat 'as relevant'. This caveat is important, as clearly all of this information would be irrelevant, impractical and inappropriate for many research projects, particularly low risk research.

9.35 'electronic consent must contain all elements of informed consent' – this needs qualification/ explanation, especially around what 'all elements' consist of. If this is the list in 9.34, this is clearly inappropriate.

9.39 A definition of 'databanks' is required. Also some explanation of 'extended or broad consent' – mentioned in the header but not explained.

9.40 It is not clear what this comment refers to – eg, acceptability to whom? Governance of what, by whom?

9.47 It is not clear how this fits within the heading 'integrated consent.' Definitions are required up front.

9.60 It is not clear how this relates to 'collective consent' discussed in section 6 or what this means for 12.27. This needs to be more closely aligned and linked to the content in 12.37-12.40.

9.59, 9.61 Please explain the legal waiver in more detail and reference the legal waiver referred to in 9.61.

9.65 covers the scenario of secondary use of identifiable data. The scenario of secondary use of non-identifiable data is not explicitly covered. More clarity is needed here (and in section on Research without consent) to cover all the common scenarios.

9.80 seems inappropriate for a Standard – is a 'may be' statement.

9.84 more detail here would be useful. In particular, discuss the limitations, who can give consent for another adult and under what circumstances. There is some information in 9.89 that is relevant.

9.90 and 9.89 This needs some more context or caveats, especially to discuss why it is included if this is not legal and who takes liability for researchers who follow this advice from NEAC, but act against the law.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

**Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

**Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

General comments on structure and content that have previously been outlined apply to this and all future sections.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

The link 'Benefits to Maori' doesn't go to any useful specific information about this – it links to Box 1.

10.23 Provide a definition of 'research protocol' and link to 11.10/11.11.

10.25 assumes that all research is reviewed by an ethics committee, which is not the case.

**Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

Standards 11.16 and 11.17 refer to researchers' capability, which does not intuitively fit under 'Research development and design'. Also, 11.17 which concerns peer review, does not fit in a section on development and design.

There is significant overlap with Standard 11.5 and associated commentary and the section on vulnerable participants. One link in 11.13 to Chapter 8 does not seem sufficient to cover this.



Not Answered

**Please outline any missing ethical issues or principles:**

Ethical considerations for the inclusion of non-binary people in research needs to be made explicit. In health research, emerging consensus around best practice for researchers engaging in sex-and-gender-based analysis involves measures with a two-step method (sex at birth and current gender) (Bauer, G., Braimoh, J., Scheim Al., Dharma, C. (2017). Transgender-inclusive measures of sex/gender for population surveys: mixed methods of evaluation and recommendations.

PLoS One 12 (5):e0178043).

Why non-binary identities matter in health research is well-detailed elsewhere, but key reasons relevant to NEAC Guidelines include: determining population size, health inequities and vulnerability and ethical considerations (Frohard-Dulent, Helene, Dobson, S., Clark, B., Doull, M., Saewyc, E. (2017). "I would have preferred more options": accounting for non-binary youth in health research. Nursing Inquiry 24:e12150).

Researchers should be able to detail how sex and gender are incorporated into research design, and to use a definition of gender that it is inclusive of gender diverse people.

The following sections of the draft National Ethical Standards Health and Disability Research Consultation document are specifically relevant:

2.8 Strategic focus on health inequities: Because sex and gender are key determinants of health outcomes across the globe (Frohard-Dulent et al., 2017), gender minorities are among the groups the consultation document refers to as "[requiring] additional access to resources to address health inequities." In order to include gender minorities, researchers need to adopt emerging practice measures. NEAC Guidelines have an instrumental role in facilitating widespread adoption.

5.8 Bioethics principles: As the NEAC Guidelines sketch, the core principles of bioethics (in partnership with Te Ara Tika principles) provide guidance for research involving Māori and Pacific communities. The Guidelines should underline the relevance of these principles for other marginalised groups, including gender diverse groups.

Beneficence – this principle holds that "health research should be designed, conducted and reported with the intention to improve outcomes" (Frohard-Dulent et al., 2017: 9). Incorporating gender into research helps improve outcomes for non-binary populations.

Non-maleficence – this principle requires attention to potential harms from health research, including the "erasing non-binary identities in research design" (Frohard-Dulent et al., 2017:9 emphasis added).

Respect for people – this principle requires autonomy in self-identifying gender identity. Where an individual's gender identity does not match their sex at birth, or with binary conceptions of sex and gender, a gender binary stands as an imposed identity and stands as a violation of autonomy (Frohard-Dulent et al., 2017: 9). Justice – this principle calls for us to ensure non-binary individuals are counted in research so that we can better understand their marginalisation and vulnerability (Frohard-Dulent et al., 2017: 9).

8.12 Commentary on potentially vulnerable participants. At the minimum, the research process should avoid contributing to factors in vulnerabilities of gender diverse groups by imposing binary gender identity and neglecting to count them by using exclusive binary gender measures. The

NEAC Guidelines should be clear: imposing binary gender identity does not do away with considerations around using potentially vulnerable participants in research.

We also want it to be clear that even when research may not be able to analyse data from gender diverse groups separately, (eg, because of small numbers in surveys), it is still important to ask about sex and gender in a way that is inclusive and not stigmatising or excluding people who are non-binary.

11.5 Standards on exclusions on the basis of gender. Related to 8.2.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

### Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

The title of this Chapter is incongruent with the content and the Standards, which entirely concern the conduct of intervention studies. The information on observational studies does not relate to any Standards, nor does the content in 12.27 onwards. This section needs extensive revision so the link between the content and Standards is clear. Much of the commentary is irrelevant to the Standards and would be easily overlooked or not found easily by anyone seeking this information.

Further Standards may need to be developed to guide the commentary on the other research designs. Eg, 'must' statements in 12.41-12.43 could form a Standard and the rest of this section provides the commentary for this.

The section on cluster randomised trials needs to be linked to the informed consent section. The Standard here appears to be that 'researchers must get informed consent from all participants in a CRT' and the commentary can discuss the reasons for this, and the options around integrated and collective consent.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

### Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

13.4 relates more to research design than research conduct.

13.11 This cannot apply to all types of research. To be more useful, could include a phrase stating something like "...at a minimum, links to websites or other social media distribution methods will be given when recruiting/meeting with potential participants or stakeholders"

13.12 only applies to trials – implicit but not clear.

13.13 is repetitive – restating 13.2

13.14 This appears to be more related to research development and does not clearly relate to the Standards 13.4 and commentary on recruitment – would fit better under research design - or at least link back to this section.

13.19 doesn't relate to any Standards. This seems out of context.

Other sections also do not clearly relate to any Standards.

13.28 Not sure what 'highlight' means/adds– maybe remove this ('emphasise' seems sufficient)

13.45 Every study does not require a safety monitoring plan. This section relates to clinical trials intervention studies and would be more appropriately included in the revised section in Ch 12, which contains Standards specific to intervention studies.

13.57 "handle it appropriately" is glib. The statement should be more active, along the lines of "...they must review affected aspects of the research to ensure that participants are adversely impacted. If they are, changes must be made to remedy this"

13.63 should be a Standard. There needs to be a more coherent and comprehensive section on privacy and confidentiality which brings all of these concerns into one place and provides clear definitions of relevant terms.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

**Charging participants**

**Please outline your reasons:**

**Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

This section is called 'Health data' in the consultation document but 'Health information' in the submission form and 'research data' in Figure 2 and 14.5.

Consistency of language and clear definitions are needed.

Overall, this section appears to assume that 'health data' are quantitative and pays little consideration to health research that is qualitative and collects qualitative data. This could be remedied by a clear and inclusive definition of health data and databanks.

**14.4 Need to define data are considered taonga.**

Major concern with this section is that many of the Standards apply generally to most or all research projects but this is not adequately signalled by the introduction of heading of the chapter. Standards are included here which should also be referenced in other sections, or they risk being overlooked. For example: • 14.6 also belongs in section 10 (see 10.4 –similar to this)

- 14.7 and 14.31 and 14.32 belong in the section on informed consent
- 14.8-14.10 belong in the section on research conduct
- 14.14 belongs in a section dedicated to privacy and confidentiality in general, which seems to be missing. As previously noted, there is no general Standard on protecting individuals' privacy and confidentiality – 13.63 needs to be made a standard not be hidden in the commentary. Also related to privacy, 14.16 needs to be made more actionable/specific, with explanation given about how researchers 'pay attention' to the context of data collection and what actually needs to be done to protect privacy. It seems inappropriate that one of the few mentions of protection of privacy and confidentiality is hidden in a bullet point in 14.52. • 14.20 belongs in the section on research with Māori
- 14.21, 14.33, 14.24, 14.25 belong in the section on informed consent.
- 14.30 Some discussion of whose responsibility it is to establish these suitable governance structures is needed
- 14.17 'pay attention to' is insufficiently directive. Some detail needed about what researchers should do in response to participants' preferences. The last sentence of this paragraph should be a standalone point as it is of general relevance – it would sit better with 14.44.

It is confusing to have a list of 'Standards' then 'Standards – data linking' then 'Standards – databanks'. Throughout the document, if some Standards apply generally to all research, and some Standards apply to certain types of research, this needs to be clearly indicated (a header is not sufficient).

It may be useful to harmonise the lists of benefits and harms from data use with the other tables on benefits and harms as the rationale to separate these is obscure. They need to be linked together more effectively.

14.21 This appears to require a waiver from an ethics committee for any "research study" involving IDI data (as one example, but there will be others). This is impractical and would slow down IDI studies to the extent of undermining one of its key strengths (ie, immediate accessibility of data to answer questions arising). These guidelines should specify whether established IDI processes around ethics are sufficient to not require such waivers (with exceptions where a study does pose clear ethical risks –see comments below on 14.48). On a practical note, need to consider what ethics committee exist for researchers to apply to for a waiver for these studies. The HDECs would not consider these, and many researchers using data such as the IDI are not affiliated with a university so cannot access institutional ethics committee review.

14.28 It is not clear how this apply to data such as that in the IDI, which is intended to hold data indefinitely, because of the application to life course research. It would be inappropriate to require IDI data, for example, to not be held indefinitely.

14.48 Standard 6.7 says all research must collect ethnicity data so this means that special consideration has to be taken for all health data – (bullet point 2). Going on from this, 14.19 suggests that all research should consider consultation. It is not clear how this recommendation fits with Section 6. Overall, this is impractically broad and would be impossible to apply in practice, particularly the bullets beginning with “may have an impact”.

14.51 Define ‘Māori data’. This should be referenced/included in section 6.

14.56 Not clear how it applies to datasets that have already been linked, eg, the IDI. If ethics committee review is required for every project using the IDI, which ethics committee will review this? What about data linkage projects that do not include health data – presumably these will not need ethics committee review? Having a ‘double’ system for health data and non-health data in this situation could incentivise research on non-health topics, to the detriment of health research. 14.63 the final sentence that ‘researchers must obtain participants’ consent’ is ambiguous and needs clarifying. This can appropriately apply to consent from participants whose data are collected via a survey or questionnaire. However, it is impractical or impossible for all participants in registries.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

Big data and new ways of using data

Not Answered

**Please provide feedback:**

## Databanks

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

See response to previous section. Clear definitions needed.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

Response number	33
Name	[redacted]
Organisation	[redacted]
Role	Scientist and bioethicist
Interest group	Academic
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Strongly Agree

#### Please outline your reasons:

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards are applicable to many types of health and disability research, but few topics can be added in categories of participants (chapter 8):

1. Research in vulnerable persons such as those with mental or physical incapacities, those who are migrants, homeless, refugees, marginalised communities (if any) or persons from LGBT community may have a potential to being exploited in research or people who are uneducated or with low economic status (These are important for India and may consider if required)
2. Research in people with terminal illness
3. Research during humanitarian emergencies and disasters

The standards balance protecting individuals with the realities of conducting research  
Strongly Agree

#### Please outline your reasons:

Can include discussion on community engagement/ partnership

The standards support researchers to navigate ethical challenges in health research  
Strongly Agree

#### Please outline your reasons:

#### Overall do the Standards?

Standards - safeguard the rights and interests of participants in research:  
Strongly Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Strongly Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Strongly Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:** Strongly Agree

**Standards - protect and reassure the community:**

Strongly Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

Mentioned under Item 2 and

Issues related to re-consent in case of tissues from paediatric donors in biobanks

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

Agree with the merging of observational and interventional study guidelines. However payment of compensation is mentioned only for commercially sponsored intervention studies. So, a brief note on compensation for observational studies can be added.

There may also be need to have a separate note on clinical trials, since there are number of issues, also on socio-behavioral research, research using traditional medicine (if any), Similarly something on ethical aspects of emerging technologies such as CRISPR, Nanotechnology,

Synthetic Biology etc **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Strongly Agree

**Please outline your reasons or suggested improvements:**



**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

Feedback provided in part two section

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The content provided under this section is helpful, clear, and relevant and workable but some more ethical considerations can be added.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

To add a suitable note on following :

1. Privacy & confidentiality
2. Transparency & accountability including publication
3. Registration on public platform such as Clinical Trial Registry
4. Community Engagement
5. Post Research / Trial Access
6. Benefit Sharing/ Commercialization
7. Benefit-Risk Assessment
8. Payment for Participation
9. Conflict of Interest10. Ancillary Care

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Strongly Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

There is scope for adding some issues

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

8.3: Researchers must justify the inclusion of a vulnerable population in the research.

8.12: Standard definition of vulnerability need to be added.

8.18 (line 9): Instead of “role of supporters (eg, friends, family, whānau)”, it is advisable to take role of LAR(Legally Acceptable representative) into consideration for decision making process

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

9.8: It can include details of researches i.e., Name, designation and contact details for emergency.

9.14: After modifying the consent form, approval from EC can be obtained to rule out ethical issues that arise from modified consent form.

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft**

**standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes: No comments Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

No comments

### **Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

11.11 (Point 2) According to WHO, Research protocol should include

- Name and address of the sponsor/funder, Name and title of the investigator(s) who is (are) responsible for conducting the research, and the address and telephone number(s) of the research site(s), including responsibilities of each.
- should specify the time that each phase of the project is likely to take, along with a detailed month by month timeline for each activity to be undertaken.
- Problems Anticipated

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Charging participants

**Please outline your reasons:**

No comments regarding points mentioned in guidelines for charging participants

### **Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Big data and new ways of using data

Not Answered

**Please provide feedback:** Yes

### **Databanks**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Human tissue**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Biobanks**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

16.5 – 16.9 Governance.

Some details about the role of Ethics committee or any other equivalent committee on governance of Biobanks can be provided (at present it is somewhat vague and mentions “a range of people with relevant interest)

For better governance, a biobank can have a technical committee with representation of both science and ethics and external members which function in parallel with the EC to govern collection of specimens, disbursement of biospecimens and data to researchers and also oversee regulatory aspects like execution of MTA or data transfer agreement for transfer of biospecimens and/or data to other institutions.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

16.29 -16.30

- Ownership of samples stored in a biobank vs custodianship.
- More details on types on consent available in a biobank would be beneficial for better understanding

### **Research with stem cells**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

This chapter 18 (Compensation for commercially sponsored intervention studies) is dealing with compensation exclusively for interventional studies (as per understanding clinical trials sponsored by Pharma companies). There can be situations where compensation need to be paid for participants of studies that are not commercially funded, student thesis, biomedical research and other public health research.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**





Response number	36
Name	[redacted]
Organisation	Auckland Women's Health Council
Role	Co-ordinator
Interest group	Consumer
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable

Agree

#### Please outline your reasons:

We believe that these standards are enormously important in guiding ethical research in the health and disability sector in New Zealand. However, the quality of the standards will only be realised with adequate oversight of research proposals by the ethics committees. It is important that their terms of reference and consideration of research proposals give full power and support to the ethical standards.

The standards are applicable to all types of health and disability research

Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research

Agree

#### Please outline your reasons:

The AWHC believes that achieving this balance will often be difficult, but that the standards must always err on the side of protecting participants/individuals even at the cost to research, particularly with regard to vulnerable participants and incapacitated people who may be sought to be involved in research.

The standards support researchers to navigate ethical challenges in health research

Agree

#### Please outline your reasons:

#### Overall do the Standards?

#### Standards - safeguard the rights and interests of participants in research:

Agree

#### Standards - promote high-quality ethical research for social, cultural and economic wellbeing:

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Neutral

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:** Neutral

**Standards - protect and reassure the community:**

Neutral

### Coverage of ethical guidance

The standards adequately cover the ethical challenges that are present in health and disability research

Neutral

**Please describe the ethical challenges that are missing:**

The AWHC believes it is difficult to ensure that all ethical challenges are adequately covered. Rapid changes in technology mean that any set of ethical standards risk being behind progress and advancement. As a result the standards must be as future-proofed as possible and the Ministry of Health as proactive as possible in dealing with ethical issues that may arise in the future. As the standards will be available only in electronic form, the AWHC hopes that this signals a regular review process for the standards to ensure that future challenges and issues are dealt with in a prompt and timely manner.

While the standards are developed primarily for researchers, we believe that they should also be accessible for members of the community who wish to access them. The standards should not be just exclusive to researchers. Therefore, it is important to ensure that the standards are also available in formats for people who have communication access needs, e.g. people who use assistive technologies to access information and people who have other difficulties with communication.

### Merging the observational and interventional guidelines

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

It makes far more sense to have a single document that covers ethical standards for both observational and interventional research, as many research proposals involve elements of both and a single document will make it far easier for researchers to negotiate and adhere to the ethical standards. We believe that the same ethical principles apply to all types of research.

### Scope of the standards and non-research activities

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

We value the way in which Te Ara Tika principles and bioethics principles dovetail and complement each other while offering unique and important contributions to the ethical standards and way in which research is conducted in Aotearoa New Zealand. The inclusion of both sets of principles, and the way in which they work together to honour the physical, emotional, intellectual and spiritual health and well-being of all our people, sets the tone for the remainder of the standards and provides important guidance for researchers.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Paragraph 5.8

We believe that the non-maleficence principle must be stated more strongly. It is insufficient to say that the “risks of harm in research should not be greater than its expected benefits.” The risk of harm should be significantly less than the potential benefits. The threshold for harm must be much higher in research in a healthy cohort and the definitions of harm (e.g. minimal harm) must not be set by any person with a vested interest in the research (e.g. anyone involved in the research). It is unconscionable that individuals might be put in a position in which greater than minimal harm is caused irrespective of how great the benefit of the research to either the individual participants or any group they may represent (future benefits to other patients/consumers). While we accept that all research, as does all medical treatment, carries an inherent potential for harm, the principle of primum non nocere must be a foremost consideration in ethical standards for research, and this cannot be overstated.

Similarly, it is not sufficient to say that researchers “must put appropriate measures in place to reduce the risk of harm”. This must be stated more strongly and to the effect that researchers “must put appropriate measures in place to minimise the risk of harm”. The use of the word reduce

in this principle is inadequate as any reduction in potential harm may be interpreted as being adequate – reduction is a relative term – and what is required is a complete minimisation of harm.

### Research involving Māori

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

#### **Please outline your reasons why the section is or is not fit for purpose:**

We agree with all ethical standards that support and facilitate research that will improve Māori health and well-being and health outcomes for Māori, and reduce inequalities and inequities in Māori health.

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Neutral

#### **Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Agree

#### **Please provide feedback with reference to the paragraph(s) in question. :**

We support the guidance provided in the ethical standards on consultation with Māori. However, we believe that it is necessary for ethics committees (not limited to HDECs, but including other ethics committees) that consider research, are tasked with approving or declining research, or providing oversight of research in the health and disability sector, include at least one member with a strong understanding of tikanga Māori and the health and disability issues facing Māori, particularly regarding inequalities and inequities, and disparities in access and outcomes.

### Research involving Pacific peoples

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

#### **Please outline your reasons why the section is or is not fit for purpose:**

We support the guidance provided to researchers regarding the involvement of Pasifika people in research and the specific cultural factors that should be considered in research involving these groups. We believe that it is particularly important that research involving Pasifika peoples is undertaken with a clear understanding of potential language barriers for some people and that patient information is provided in a way/language that ensures that they are able to provide fully informed consent to their participation.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

#### **Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

It is difficult for us to be sure that all relevant ethical issues and or principles for health and disability research in New Zealand are covered in this section, but we appreciate the extensive list of potentially vulnerable participants and the particular emphasis on their increased risk of harm, the need to protect such participants and minimise harms to them.

In relation to people with disabilities being identified as 'vulnerable', we agree that research does show that people living with intellectual, visual and hearing impairments are vulnerable to abuse. However, we would argue that the standards promote a lack of disability awareness among the research community, as one of the biggest abuses that these people experience in the health system is of their right to be fully informed. Information is not made accessible to them. It does not come in alternative forms, such as NZ Sign Language or Easy Read English. We want the standards to be inclusive and to see in the standards that explicit mention is made of the need to ensure that information is accessible to people who have visual impairments, literacy issues or who are New Zealand Sign Language users.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Paragraphs 8.15 – 8.19 Diminished Capacity to Consent

We have specific concerns about the inclusion of people with diminished capacity to consent. Essentially we believe that only people who can make a fully informed decision to participate in research should be asked to participate; people who clearly understand that they have a choice, understand the probable benefits, risks and side-effects, what the research entails and what is expected of them in terms of time, travel, participation in research activities, and can consent to these without coercion and duress.

Our Code of Health and Disability Services Consumers' Rights still allows for research on adults not capable of providing fully informed consent on the basis that the researcher decides it is in the consumer/patient's best interests. The AWHC does not believe that researchers are capable of making an unbiased decision that is truly in the best interests of the consumer/patient.

In terms of supported decision making, this issue is fraught as family/whānau of vulnerable patients/consumers may be subject to potential coercion and duress. Most want what is best for their loved ones, but may not be best placed to make important decisions regarding research of which they may have little understanding, in particular if they harbour hope that there will be significant benefits for the participant.

We understand the need to undertake research that might generate knowledge that may improve the lives of the participants or similar cohorts of people in the future. However, this must be balanced against the rights of, and protecting from harm, those research participants. When research participants have diminished capacity to consent then the right to protection from harm must necessarily be higher.

#### Paragraphs 8.26 – 8.29 Research in Children and young people

We are concerned that research involving children and young people be as limited as possible and only when absolutely necessary. An issue that is not discussed is the adverse impacts of normalising medical intervention for children, when the behaviours that should be modelled for children are healthy lifestyles and choices, and disease prevention. Some studies can imply that normal life is riddled with issues that require medical intervention and that normal life events are diseases or conditions that “should” be cured or remedied. This is not helpful in raising resilient, healthy people but instead encourages an attitude that health comes from drugs and procedures.

#### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

#### **Please outline your reasons why the section is or is not fit for purpose:**

While we agree, we repeat here the point that we have made previously: we would argue that the standards promote a lack of disability awareness among the research community as one of the biggest abuses that people with disabilities experience in the health system is of their right to be fully informed. Information is not made accessible to them. It does not come in alternative forms, such as NZ Sign Language or Easy Read English. We recommend that explicit mention is made of the need to ensure that information is accessible to people who have visual impairments, literacy issues or who are New Zealand Sign Language users.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

#### **Please outline any missing ethical issues or principles:**

It is difficult for us to be sure that all relevant ethical issues and or principles for health and disability research in New Zealand are covered in this section. However, the discussion on issues of informed consent appear to be thorough and provide substantial guidance to researchers regarding the necessity of obtaining truly informed consent and the information that must be provided to potential participants to enable them to make informed decisions. Of particular importance to the AWHC are the sections on harms and rights (para 9.34).

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question: Para 9.42-9.46**

**Withholding information and deception**

We have concerns about the withholding of information and/or deception of participants as part of the study design, and believe that these methods should be used rarely and only with significant ethical oversight. While we understand the need to withhold information or temporarily deceive participants for specific purposes, in essence these practices are the antithesis of informed consent, and truly informed consent cannot be said to have been obtained in these situations. There must be extenuating and unavoidable circumstance for such practices to be approved.

**Para 9.52-9.57 Abbreviated consent in medical emergencies**

We are concerned that abbreviated consent in medical emergencies places potential participants in the position of consenting under duress or in a coercive or perceived coercive situation. There must be overwhelming benefit to the participant relative to potential harm in such research, and considerable ethical oversight of such research to ensure that rights and welfare of the participants are foremost.

**Para 9.62-9.64 Opt-out Consent**

We oppose opt-out consent and have concerns about the tendency of many potential participants to “just go along with” what is proposed. Many people take the path of least resistance or avoid the sort of conflict that they feel may arise by asserting their right to opt-out in such situations. We also have considerable concerns about the use of the term “minimal risk” as this is a highly subjective and relative term, and inherently cannot be quantified. “Minimal risk” is very much an “in the eye of the beholder” term and we have considerable concerns about who it is that determines that the research carries no more than minimal risk to participants; this should not be decided by anyone who has a vested interest in the research, e.g. the researchers themselves.

It is difficult for us to foresee a situation in which researchers complying with all the requirements of paragraph 9.64 cannot simply obtain opt-in consent from the participant.

**Research with participants who are unable to consent**

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

We believe that the ethical guidance in the draft standards provides clarity to researchers and importantly encourages researchers to check the relevant legislation and seek legal advice. However, we would like to add to this response.

The AWHC would like to make clear our philosophical opposition to conducting medical experiments, including within the auspices of clinical trials, on any New Zealanders without their fully informed consent. That vulnerable groups of consumers can, and are, being exploited for research gain under the current law goes against the principles of the Nuremberg Code (1947), the founding document that gave rise to modern medical research ethics. It is clear that the law as it stands is sufficiently weak and uncertain as to allow studies to proceed in relation to participants who are unable to consent if participation in the research is in their “best interests” where the researcher is able to make the decision as to what constitutes in the patients “best interests”.



The AWHC believes that absolutely no incapacitated/incompetent adults should be enrolled for medical experiments/clinical trials/research until there are sufficient protections and safeguards established in law that first and foremost protect their rights and interests, health and well-being.

The Nuremberg Code (1947) on medical experimentation on human subjects was followed by the Geneva Convention and then the Declaration of Helsinki formulated by the World Medical Association, of which the New Zealand Medical association was and is a member. The Declaration of Helsinki clearly states that: • “while the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects”;

- “some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm... All vulnerable groups and individuals should receive specifically considered protection.”
- “participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.”

Yet despite these existing protections, which New Zealand’s Medical Association ratified, medical experimentation on competent women at National Women’s Hospital occurred without their knowledge or consent in the 1960s and 70s.

Our Code of Health and Disability Services Consumers' Rights, while a step in the right direction, still allows for research on adults not capable of providing informed consent on the basis that the researcher decides it is in the consumer/patient’s best interests. The AWHC does not believe that researchers are capable of making an unbiased decision that is truly in the best interests of the consumer/patient. In addition, it is the AWHC’s view that the current Health and Disability Ethics Committees (HDECs) do not prioritise the protection of research subjects. It should not be left to a researcher to “balance the risks of harms with benefits” and permitting researchers to make these decisions is grossly insufficient protection for incapacitated research subjects.

Once an adequate ethical and legal framework is in place (including specific definitions of terms such as “minimal risk/burden”, “benefits”, “best interests”, and who constitutes an authorised legal representative) further nationwide discussion involving all stakeholders, including patient and consumer advocates, should revisit the circumstances, if any, in which research involving vulnerable groups such as incapacitated/incompetent adults might be permitted.

If an adequate ethical and legal framework was established that provided sufficient protections for incapacitated/incompetent research subjects, including a Special Ethics Committee to oversee approval to such research proposals, the AWHC may change its stance on the involvement of incapacitated people in medical research. **Deception**

#### **NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

While we have concerns about the use of deception of participants as part of the study design, and believe that these methods should be used rarely and only with significant ethical oversight, as far as we have the ability to determine the guidance provided in the draft standards meets research needs.

#### **Research benefits and harms**



The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Paragraph 10.2, 10.4 and 10.7

The concept of the greater good – or the potential benefits to society and science – must be secondary to the rights and protection of individual participants. There can be no situation in which the benefit to society and science is given a greater value than the individual and no individual should be sacrificed at any level for “the greater good”. Notwithstanding that all medical treatments and procedures, and by extension all medical research, carry some risk of harm, the protection of the health and well-being of participants should be the foremost consideration. It is insufficient to say that “To justify any risks of harm to study participants, the research must have social and scientific value” as significant harm such as death or disability for any individual cannot be justified just because the research has social and scientific value. Mild, transient and localised harm/side-effects may be acceptable to some individuals when balanced against the generation of knowledge with social and scientific value. However, it is a matter of degree and it must be up to the potential participant to determine the risk she/he is prepared to accept to assist with the generation of knowledge with social and scientific value. This section should be reworded to ensure that this concept is understood by researchers.

Paragraph 10.12

While there may be few research proposals in New Zealand of the kind to cause serious physical harm, the risk of death or permanent disability is not unknown. There are well known clinical trials in which severe injury and death have been documented, including the highly publicised 2006 clinical trial of a cancer drug in the UK which left six previously healthy men fighting for their lives with multiple organ failure and with at least one having fingers and toes amputated and all men being told that they were at risk of developing cancer or auto-immune diseases as a result.

We have our own significant history of medical experimentation that caused women permanent injury including death in Herbert Green’s cervical cancer experiment.

The physical harms listed in this table must include death and permanent disability as examples of harm, and to not include these is remiss.

Paragraphs 10.15 – 10.21

Researchers must ensure that potential participants do not acquire an inflated impression of the potential benefits of participating in research, such that they may be willing to risk greater potential

harms because they perceive that the benefits are greater than they really are. All discussions with, and information provided to, potential participants (written and verbal) must be absolutely transparent, couched in plain language and err on the side of caution/overstating the potential harms to ensure that potential participants have as complete an understanding as possible of the risks of taking part in the research.

## Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:** Para 13.25 – 13.28

Advertising

We value the guidance provided in this section and place a high importance on advice to researchers not to advertise the research to potential participants in such a way as to “cause potential participants to underestimate or dismiss their risk of harm”, or to overtly appeal to potential participants’ sense of doing public good by participating.

Para 13.29-13.36 Social Media

While we don’t oppose the use of social media to advertise the research to potential participants, and understand the value of social media in communicating with a target audience, we also believe that people are often unduly influenced by information they access on social media and in particular may be influenced by comments left by other users. Use of social media should be done with care and with considerable regard to the issues and disadvantages/negative impacts that are inherent in engaging with social media.

Para 13.37 – 13.39 Reimbursements, koha and incentives for participants

We believe that it is important to strike a balance between not providing such a high incentive to participation that such incentives have a coercive effect and impact on the ability of potential participants to make truly informed decisions about participation, and ensuring that involvement in the research does not cost participants. This is especially important for vulnerable cohorts/participants. Many New Zealanders or those representing groups of New Zealanders who could ultimately most benefit from research (e.g. diabetes, obesity and other conditions influenced by lifestyle and poverty) are in areas of higher deprivation and it is important that they are not

disadvantaged in any way at all by their participation, including but not limited to such issues as transport to and from appointments, costs of childcare if necessary, taking time off work, etc.

#### Para 13.40-13.44 Managing conflicts of interest or role conflict

It is the experience of members of the AWHC that not all health practitioners (some of whom are involved to a greater or lesser extent with research) are fully cognisant of potential conflicts of interest or downplay such conflicts. All people involved with research should err on the side of overstating conflicts of interest. Of considerable concern to us is the issue of subjective assessments on the part of researchers particularly in establishing “minimal risk” and “best interests” as significant conflicts of interest are present when a research has a vested professional, personal, reputational, or financial interest in the progress and outcome of the research.

#### Para 13.47-13.48

We believe that that DMC should be 100% independent of the study team in order to be able to effectively monitor and impact on safety of participants. In addition, we believe that having a trial management group that may comprise only the principal researcher will not be sufficiently objective and that trial management groups should include at least another person or some sort of institutional reference group to whom the PI should report.

#### Para 13.51-13.53 Responsibilities for adverse event monitoring

The monitoring of adverse events is extremely important and we believe that the language in this section must be strengthened, and “shoulds” must become “musts”.

#### Para 13.56 Terminating a study

This paragraph should read “Therapeutic studies where participants are potentially receiving therapeutic benefit must not be terminated simply for reasons of commercial interest.”

#### Para 13.73-13.76 Interpreting and presenting study results

We value the sensitivity of the guidance to researchers in this section and agree that deficit thinking and victim blaming should be avoided. The language used in presenting and discussing the results of research is important and much consideration should be given to this aspect of the research by researchers and authors.

#### Para 13.77 Returning results and incidental findings

We are concerned that participants should not be disadvantaged or negatively impacted by the results of the research or any incidental findings. Such outcomes should be anticipated by the researchers and protocols must be established and included in the research design for handling such potential adverse impacts for participants.

#### Charging participants

**Please outline your reasons:**

We strongly oppose the charging of participants for any part in research. We do not agree with the statement that “the research has a very high likelihood of generating benefit to the worst-off in society in the long run” provides any justification for charging participants. No participant should be expected to pay because there is a perceived (and not yet realised or guaranteed) downstream benefit to the worst-off members of society. In essence, we do not agree that the draft standards provide a high enough barrier to allow for any charging for participation. If the research is so important that it must be carried out, the onus should be on the researchers or the wider community to ensure that funding is found to enable it to go ahead and no individual participant should be charged.

## Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

### Please outline your reasons why the section is or is not fit for purpose:

We believe that this section is clear and relevant and thorough in the guidance that it provides to researches on protecting and curating participants health information, in particular the consideration of and definitions of the identifiability of data.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

### Please outline any missing ethical issues or principles:

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

### Please provide feedback with reference to the paragraph(s) in question:

Big data and new ways of using data

Not Answered

### Please provide feedback:

## Compensation for commercially sponsored intervention studies

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly Disagree

### Please outline your reasons why the section is or is not fit for purpose:

We believe that all participants in medical/health research should have ACC cover and access to no fault compensation and rehabilitation entitlements, whether the clinical research is publicly or commercially sponsored. However, we realise that for this to happen a law change would be required.

While the new draft standards appear to strengthen the protections for participants, and improve the amount of information given to potential participants, they are still not adequate.

We believe that all commercially sponsored studies must be required to provide adequate no fault compensation and rehabilitation entitlements. Commercially sponsored research that does not

include such provisions must not be approved in New Zealand. The provision of compensation must be legally enforceable and participants must not have to engage legal representation in order to obtain compensation for injuries or harm sustained as a result of participating in research.

While the guidance in the standards requires greater transparency on the part of researchers and their commercial sponsors, there is still a lack of compulsion or enforceability to provide compensation even if the sponsors are required to provide evidence of holding adequate insurance. Injured and harmed participants must not have to fight to get just and reasonable compensation for their injuries.

Under the current situation, we also do not believe that most participants/potential participants are made sufficiently aware - before they consent to participate - of their vulnerability in the event that they sustain an injury as a result of the research in which they participate. Recent changes in the PIS template text regarding compensation in commercially sponsored research have improved the situation, but this is still inadequate.

The underlying principle is that there should be no cost – financial or to their health and well-being - to participants for their participation in research no matter who is sponsoring the research, and in the knowledge that the risk of harm, no matter how small, still exists in each and every study, any participant harmed in any way should be compensated for that harm.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

Please refer to our answer to question 53 above.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Please refer to our answer to question 53 above.

Response number	37
Name	[redacted]
Organisation	[redacted]
Role	Research Office Manager
Interest group	Government agency
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:**  
Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

Is the scope of the document clear?

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

The contrast to Te Ara Tika is entirely based on "Principlism", and it should be mentioned that this is merely the current working ethical basis of medicine. There are other approaches (eg based on broad ethical theories such as utilitarian or relationship ethics, or alternatively consequentialist or causticity approaches) from within the Western philosophical tradition, and obviously other ethical concepts/approaches from other cultures, in particular Confucian/Taoism from China.

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?

Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

Box 1, paragraph 4

"Institutional Ethics approval"- in hospitals we don't have institutional ethics and this should be applicable all across the board. I believe the term 'locality ' would be more appropriately used as it will be locality that will be final check point for the studies.

### **Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Chapters 10 is readable and workable. They seem to cover the relevant issues other than points I raised below

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**



Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

When considering the benefits and harms of research, it should be made clear to everyone (ethics committees, researchers, clinicians, patients or volunteers) that not participating has similar benefits and harms. Routine clinical care, where there are research questions still open, is arguably more harmful than being in a clinical trial. This consideration should be made explicit when considering research harms - particularly in research design (inclusion/exclusion criteria) and when considering the ethical acceptability of research.

### **Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

It is fine although the inclusion/exclusion criteria mentioned below should be considered.

When considering the benefits and harms of research, it should be made clear to everyone (ethics committees, researchers, clinicians, patients or volunteers) that not participating has similar benefits and harms. Routine clinical care, where there are research questions still open, is arguably more harmful than being in a clinical trial. This consideration should be made explicit when considering research harms - particularly in research design (inclusion/exclusion criteria) and when considering the ethical acceptability of research.

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Chapter 12 - Incremental testing in early-phase trials

"escalating risk incrementally" - risk is not escalated; incremental steps are made each of which contains a similar amount of risk, as the previous steps have been safe.

**Commercially sensitive information, please let us know where:**

Response number	39
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

The standards are applicable to all types of health and disability research  
Strongly Disagree

#### Please outline your reasons:

The guidelines specifically address human tissue research but the definition of human tissue excludes micro-organisms isolated from human tissue samples. This is good however no guidelines are available covering research on or banking of human-origin micro-organisms. Explicit ethical guidance on this topic would be helpful and seems to be absent from the guidelines.

The standards balance protecting individuals with the realities of conducting research

Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research

Agree

#### Please outline your reasons:

#### Overall do the Standards?

#### Standards - safeguard the rights and interests of participants in research:

Agree

#### Standards - promote high-quality ethical research for social, cultural and economic wellbeing:

Agree

#### Standards - reflect the principles of the Treaty of Waitangi:

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

Working with micro-organisms isolated from human samples.

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Neutral

**Please outline your reasons:**

The standards provide a good framework for conducting both observational and interventional research, however the complexity and size of the integrated standards documentation may discourage some health practitioners from conducting audit or observational studies, which is a required part of practice in medicine.

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Disagree

**Please outline your reasons or suggested improvements:**

Research offices will routinely default to the most stringent requirements, meaning that audits and other related activities are often required to be submitted for review rather than locally approved. Failing to clearly determine what an activity is will ensure that there are more barriers to audit and related activity (which are a required part of practice of medicine), which it could be argued is unethical. In my view, retrospective access by employees of a healthcare organisation (who are bound by confidentiality agreements and professional standards) to data collected by that organisation for the purposes of providing healthcare, should be able to be clearly defined as minimal risk and not requiring ethical review, subject to local research office approval, with stringent requirements for ensuring that individual patients are not identifiable from presented data.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

9.16 "6 Consent must occur before study processes begin, including personal data collection and diagnostic testing necessary for eligibility screening." appears to preclude the use of any means of identifying potential participants and is totally unworkable. If consent must be sought before screening how can anyone be screened for eligibility? This also conflicts with 13.21 which allows for review of notes or data to identify or screen potential participants. I believe that 9.16 is an attempt to ensure that study-related interventions such as performing additional tests (i.e. not part of routine care/already performed) required for screening for eligibility for a study are not performed without consent which is completely reasonable however if this is the intent of 9.16 this needs clarification in the text.

### **Research with participants who are unable to consent**

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

### **Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

Response number 40

Name	[redacted]
Organisation	[redacted]
Role	Research Fellow
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

The content itself is good, and a big improvement on the previous standards.

This is, however, a very long document and I expect many researchers will only read the sections they consider relevant. With this in mind, it would be helpful to explicitly state at the beginning of the document which sections are relevant to ALL health research, so that researchers don't, for example, skip the "Research involving Māori" section when they are researching a broad NZ population, that includes but does not specifically focus on Māori.

It would also be useful to include something like page numbers with the hyperlinks, to assist anyone that has printed the document.

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

These standards seem to have a good balance, however, the broader research environment in which these standards operate seems to be extremely biased in favour of researchers. The system needs to be altered to make it easier for participants/community representatives to have direct feedback into an ethics application and for them to be able to easily complain if they feel the researchers have breached the ethical approval. Currently, I doubt that most participants/community representatives would know where to go for concerns related to research ethics (unless they still have their participant information sheet readily available). Note that all progress reports to ethics committees are done solely by the researchers, with no requirement to show that the community/participants are happy with the progress of the research.

The standards support researchers to navigate ethical challenges in health research

Agree

**Please outline your reasons:**

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:**

Neutral

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Neutral

### Coverage of ethical guidance

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

Generally this is good, but there are some sections that need further work. Further comment on this will be made under the relevant sections.

### Merging the observational and interventional guidelines

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

I think it is a big improvement having one document - this will make it much easier for all the studies that include a mixture of observational and interventional research.

### Scope of the standards and non-research activities

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

I love the inclusion of Te Ara Tika in this section.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

There are many (at least tens, if not hundreds) ethical principles that are relevant to health research or specific health research projects. It is not practical to include all of them in a document like this. I think, between the two sets of four, a good range has been included.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Agree



**Please provide feedback with reference to the paragraph(s) in question. :**

Why does the 'research involving Māori' section seem to be the only one without the question "Do you have any comments on specific paragraphs..."? Since you have not provided such a section, I am answering that question here:

6.7 - I find it odd that there is a requirement to collect ethnicity data, but no associated requirement to use this or make it available in any way.

6.15 - the statement to engage with people that "have sufficient knowledge to play a meaningful role" could be open to interpretation. For example, a researcher could use this to justify consulting with someone that is an expert in the research area, but knows nothing about the community, as community members do not have 'sufficient knowledge' about the research.

6.16 - while this is a good statement in theory, I'd like to note that the current set up of our research system can be a major factor in 'developing a long-term relationship', as projects are typically only funded for a couple to a few years, with no guarantee of further funding to support the 'long-term relationship' between researchers and community.

Box 1, page 22, in the 'minimum expectations' section

- 'earliest stages' could be open to interpretation. I would specify 'before ethical approval is in place'.
- while it is ideal that consultation happens as ideas are developing, there are practical issues with the current system that make this difficult. Consultation costs money, whereas most funders will not provide financial support for a project until after the ethical approval is in place. Also, consulting as early as possible in the current environment runs the risk of getting the communities hopes up, only to have potential funders repeatedly turn the project down, until the researcher is forced to move onto another project that is more likely to get funding.
- Need to add requirement to consult with multiple groups after "In some cases there may be more than one governance group"

Box 1, page 22, in the 'kaupapa Māori' section

- the last sentence of the first paragraph and the first sentence of the second seem to contradict each other and there is "a broad range of research methodologies" in the first, but specifically "Māori methods" in the second.

**Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

9.33 - this section seems to indicate that participants may overestimate the benefit of a study (which I agree with), however, I am also concerned that researchers themselves often

overestimate benefits. Researchers often have to talk up the positive aspects of the study, for example, to gain funding, and this way of thinking might then be continued when writing participant information sheets and/or when directly communicating with participants (or other people that will be communicating with participants). It is important that this bias is recognised and that researchers ensure they are providing accurate information - perhaps by seeking input from other researchers in the field that are not directly involved in the study.

### Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

I think the draft standards provide fairly good ethical guidance, given the difficulty of the situation. My only suggestion is to put stronger emphasis on "not currently able to be conducted within the law" in 9.90, so some skim reading would not just read the two bullet points.

### Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

I am unlikely to ever need to use deception in my area of research. I appreciate that some research does require this and I think the draft standards allow this, while giving appropriate protection to participants.

### Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

14.4 - I would argue that most "data is seen as taonga", not some, as most data includes one or more Māori participants, or includes something else important to Māori such as NZ plants, water etc.

14.11 - I agree that participants' data needs to be protected, but increasingly international journals require data to be made publicly available. Although this data will be in a form where the participants are not identifiable, making data available even in this form is still often in conflict with the beliefs of Māori and many other NZers. It would be good to have more explicit guidance on this in the standards (I personally think that protecting participant rights should come first, and data should only be made publicly available if the participant has consented to this).

14.20 - "Māori data" needs to be defined somewhere, in particular, that it does not just relate to data collected in Māori spaces like marae, or just to people, but to anything considered important/taonga to Māori.

14.22 - specify 'only', i.e. "... sent overseas for research [only] if the person..."

14.32 - the "limited circumstances" clause of this sentence seems contradictory to the purpose of data banks.

14.42/14.43 - the two tables in these sections do not seem to convey similar information, despite the similarity of their titles. In particular, Table 6 seem overly focused on harms to individuals, with harms primarily at the group level all bunched together in the last category 'interpretation harms'. Given that research has a history of failing to consider harms at a group level (especially with indigenous and other minority populations), I fear this table is going to make the situation worse.

14.48, third bullet point - this bullet point implies to me that genetic research is the only kind that can cause stigmatisation. This is not the case and there has been a long history of harm coming from epidemiological research that portrays some ethnic groups as lazy, overweight etc.

14.49 - 'whakapono' and 'whakatauk■' have not been defined anywhere within the document. I am not sure what you mean by 'whakatauk■' in this context, as it does not seem to fit with my understanding of the word.

### Big data and new ways of using data

Agree

#### **Please provide feedback:**

I like the new data identifiability groups and that it's explicitly stated that linking data may result in individuals becoming identifiable.

### Databanks

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

#### **Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

#### **Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

#### **Please provide feedback with reference to the paragraph(s) in question:**

### Human tissue

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

#### **Please outline your reasons why the section is or is not fit for purpose:**

Most of this section is fit for purpose, however, the "Gene editing" sub-section is not.

The Gene editing sub section in this draft document seems to only consider the use of gene editing technology with embryos. Gene editing, however, can be conducted with any cell type, including, but not limited to bone marrow stem cells, adult cells that have been transformed to stem cells, foetal or umbilical stem cells - any cell can potentially be modified using gene editing techniques. Given the limited availability of embryonic stem cells, this technology is far more likely to be put into use in humans with adult cells. This gene editing research with (adult) human cells has not been considered at all in these standards. There needs to be guidance for:

- when any human cells can be modified in this way,
- when cells can be taken from patients for this type of research,
- when modified cells can be transferred into patients as a potential therapy.

Note that any genetic disease that primarily affects only one or a few organs can potentially be cured at stages of development after 'embryo'.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

In addition to the comments on the gene editing section (above):

15.23 - I think this should be worded so that it's clear human tissue should ONLY be sent overseas if the participant has consented.

15.44 - make it clear here that continued consultation is also expected.

15.47 - I think 'Māori embryos' is too narrow. Other groups (ethnic, religious etc.) will also have tikanga that they may want followed when their human embryos are being used. Additionally, Māori interests are not restricted to embryos, and any tissue obtained from Māori participants should prompt researchers to consider these principles.

Response number	41
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Neutral

#### Please outline your reasons:

Overall it is a worthy and well considered document.

We have some strong concerns with use of commentary to pre-empt/justify the new draft NEAC position, which is (a) not necessary for a Standards document; (b) could limit the application of the new draft NEAC Standards clause intention by inferring specific use or application; and (c) makes it more challenging to quickly use/refer to the new draft NEAC Standards compared to the 2012 edition. This was most evident in Chapter 9; but is present throughout the new draft NEAC Standards. It is for this reason that we question it's ability to be "helpful, clear, relevant workable".

Clause 3.20 defines a researcher and coordinating investigator. This is not aligned to Medsafe or current GCP terminology. Propose terms align strictly with GCP to remove ambiguity.

The standards are applicable to all types of health and disability research  
Neutral

#### Please outline your reasons:

The intended application of the new draft NEAC Standards is not clearly defined in the introduction and terms/definitions are lost within the document. For example - you have to get to Chapter 12 before you learn of the types of studies, and it remains silent on audits and registries.

The standards balance protecting individuals with the realities of conducting research

Strongly Disagree

#### Please outline your reasons:

Our site has previously stressed to the HDEC/HRC that NZ participants are inadequately protected in the event of a commercial trial-related medical injury.

Chapter 18 addresses the compensation issues (and we commend their inclusion)however changes made are arguably pointless if HDEC or another party (?) does not have the authority to police them - specifically clauses 18.5 and 18.6 . If the intention stands that HDEC will hold the Sponsor accountable in the event of a claim, then there is merit in including these clauses. Our concern is whether HDEC will have the resource, intent or compulsion to action support for these

participants - which is desperately needed. While we accept these are rare occurrences, when they do occur the impact can be catastrophic and any assistance made by the site/investigator will null and void the Sponsor's requirement to compensate at all. This leaves the participant isolated, unsupported and in limbo. We need to protect NZ citizens who are generous enough to participate in commercial clinical trials and urge deeper consideration is given to managing this current limitation.

The standards support researchers to navigate ethical challenges in health research

Agree

**Please outline your reasons:**

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Strongly disagree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Strongly disagree

**Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

**Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Neutral

**Please outline your reasons:**

The document remains silent on audits and registries.

## Scope of the standards and non-research activities

Is the scope of the document clear?

Neutral

**Please outline your reasons or suggested improvements:**

Silent on the topic of registries.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

Some clauses appear to be deliberately vague to broaden their potential application (eg 4.5). It will be challenging for HDEC to translate these into SOPs.

## Ethical principles

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

## Research involving Māori

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?

Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

Clauses 6.11-6.16 we accept the importance of early consultation when designing a research project. In the case of commercial global clinical trials, the protocol is finalised and will not be amended for local application, making the application of these clauses very challenging. We propose adding a new clause acknowledging this where local changes are usually applied to the PIS/CF, following consultation with a Maori research consultant.

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Clause 8.39 - Query - there is a preference to use the term "unborn child" instead of foetus. Suggest making this change.

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)



Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

There are a number of aspects missing

- Registry participation and consenting requirements
- Clinical Trials requiring the collection of biological samples for broad future biomarker/genetic analysis should be presented with a PISCF opt out section or as a separate consent to the main study.
- An expectation for specific details of planned future biomarker/genetic analysis should be well defined - eg term of sample storage; where the samples are stored; scope of research permitted on the samples.
- Consideration for withdrawal of consent. We request a clause be adding preventing commercial global Sponsors from "stalking" past participants on open socialmedia after a participant has actively withdrawn consent.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

9.35 Language is prescriptive; need to remove first sentence and stay very broad. There's mention that all "elements" must be included - this could be challenging for e-consents generated overseas?

9.47 Learning Health care systems - what are these? Question need for opening paragraph?

9.49 Could the opening use of the word 'pragmatic' be replaced by the word 'practical' given that there is reference to pragmatic trials so this could cause confusion

9.60 Should include the term Pragmatic trials here in the second sentence.

Clause 9.51 and 9.60 are not in perfect harmony. If a valid argument in favour of a waiver (where all precedents are met) clause 9.60 should also scope for this perhaps using the term "improbable" rather than "is not possible". Or, simply remain silent?

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

Yes

Propose that the PISCF template for unconsentable patients (eg some ICU/ED studies) be amended to allow scope for an independent doctor to assess and confirm that participation in the clinical trial is in the patients best interest.

Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

NA

## Research benefits and harms

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

## Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Under clause 11.2, we propose clarification of the opening sentence "Researchers must be suitably skilled and resourced .. .."

We are not clear on how you define "suitability skilled". We suggest one element should be recent GCP training, and that it should be proven to the HDEC committee by a GCP training certificate that is less than 2 years old.

The updated ICH GCP Edition 6 Version 2 was released in June 2017 and further clarifies the investigator responsibilities and the importance of this role in conducting quality clinical research. It would therefore be appropriate if these expectations were applied to all NZ investigators performing research in NZ.

## Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

Audits should be specifically mentioned under clause 12.7-12.9 "Observation studies" Registries

are not clearly covered and need to be included in this section.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

As mentioned above - registries (in all their forms) and audits need to be included.

There is a header "Ethical Issues in Newer trial designs" followed by clause 12.28. It would be helpful to have a similar head for all the subtypes of trials, and that clearly outlines all elements that should be considered. For eg - use of placebo in an interventional study where the placebo group is not receiving Standard of Care treatment.

This is a key section that investigators will read, and it will be closely tied to the completion of the HDEC application form. More structure and clearer guidelines in this section will mitigate many interpretation issues downstream. We also ask that the HDEC translate potential audit submission with an abbreviated application form and expedited review process.

## Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

As mentioned in comments made for Chapter 11 re GCP, we believe Chapter 13 should also be tightly tied to GCP training, and this could be captured somewhere around clause 13.2.

Clause 13.45, Monitoring Studies, states that "every study" requires a safety monitoring plan. This is a broad requirement as many studies may not require a safety monitoring plan - eg observational studies; retrospective analyses/audits. It would be helpful to explain what elements are expected/required for specific types of studies - current wording is too light.

Clause 13.51 AE events. Is there an intended change of position re AE reporting (ie AEs/SUSARs are generally not currently submitted/reviewed by HDEC, only reported on the specific request by a PI/Sponsor). Clause 13.52 requires prompt reporting of SUSARs and SAEs - but to whom? Currently they are sent to Medsafe - is the expectation that they will also be submitted to HDEC?

Clause 13.56. We commend the inclusion of this clause; can you comment on how this will be enforced?

Clause 13.80. The concept of consenting patients at 2 timepoints that they wish to receive study results is clunky. The second timepoint (why is a second timepoint even needed?) should arguably be the participant's final visit. What elements of information should be shared and in what circumstances can this be released without HDEC approval? Should this correspondence be managed by the lead site (preferred) or on a site by site basis? **Charging participants**

**Please outline your reasons:**

We are not aware of this circumstance, or how it is applied. We cannot comment.

**Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

It's great to see NEAC taking a strong position on health information

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

- Registries - again, the document is silent on this study design. Encrypting data will be key for large databases.
- Clause 14.20 There is a new requirement that researchers "must" involve Maori in the governance of Maori data. How does this translate into process?
- Data in social media, put out in the open domain is not touched on. Should it be explored in this Chapter? A couple of specific considerations:

- \* Can an investigator withdraw a study participant who is talking too openly in social media about a clinical trial (where they could jeopardise study blinding or creating a bias)?
- \* Advertising on social media, with targeted strategies to identify patients based on their social media activity. Is this accepted?
- \* Contacting potential participants through social media - rather than by traditional models such as post, email, phone and text.\*

Big data and new ways of using data

Agree

**Please provide feedback:** No missing risks identified

## Databanks

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

## Human tissue

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

Do we need to also consider a Pasifika position on tissue sampling?

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

GMO medicines are slowly presenting as new clinical options. Management of human tissues that may include GMO medicines/other health risks (eg virus/disease) should be mentioned in this Chapter

## Biobanks

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

The opening clause 16.1 could be interpreted to mean that any fridge/freezer/shelf/dish that has a human tissue sample in/on it for even 1 minute would be defined as a biobank.

Does this definition mean that every fridge and freezer at a clinical trial site is considered a biobank?

If this is not the case, then this definition needs tightening up. We would suggest that the definition is too loose, and perhaps could be modified to include a third bullet point:

- where the custodian is the party who will contract/perform the intended analyses.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Clause 16.15 = who would enforce that governance of tissue banks is followed.

## Research with stem cells

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

## Compensation for commercially sponsored intervention studies

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

Chapter 18 addresses the compensation issues (and we commend their inclusion) however changes made are arguably pointless if HDEC or another party (?) does not have the authority to enforce it - specifically clauses 18.5 and 18.6 . If the intention stands that HDEC will hold the Sponsor accountable in the event of a claim, then there is merit in including these clauses. Our concern is whether HDEC will have the resource, intent or compulsion to action support for these participants - which is desperately needed. While we accept these are rare occurrences, when they do occur the impact can be catastrophic and any assistance make by the site/investigator will null and void the Sponsor's requirement to compensate at all. This leaves the participant isolated, unsupported and in limbo. We need to protect NZ citizens who are generous enough to participate in commercial clinical trials and urge deeper consideration is given to managing this current limitation.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:** See above

Response number	42
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Strongly Agree

#### Please outline your reasons:

Clearly much thought has gone into content and logical order of sections and includes references to other relevant sections.

Could be useful to colour background differently for the standards and commentary like in Health Information Privacy Code

The standards are applicable to all types of health and disability research  
Strongly Agree

#### Please outline your reasons:

Appears to cover a broad range. Covers the studies we have experience in.

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

For clinical trials with investigational medicine it is important to balance risk to privacy with risk to safety – dangerous to remove personal identifiers to protect participant privacy if it results in wrong medication being administered or being unable to identify correct records in the event of a medical emergency.

The standards support researchers to navigate ethical challenges in health research  
Strongly Agree

#### Please outline your reasons:

Clear guidelines across a range of topics **Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**



Agree

**Standards - reflect the principles of the Treaty of Waitangi:** Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

Balancing risk to privacy with risk to safety in investigational medicine trials (as noted above)

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

Good combination or comprehensive guidelines with removal of duplication

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Strongly Agree

**Please outline your reasons or suggested improvements:**

Sets out what the standards do apply to, what they don't and that ethics relevant to all.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

For previous section, 3.9, could mention ICH-GCP E6

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Difficulty identifying reviewer(s), additionally as each country has own culture, rather than one reviewer encompassing entire Pacific .

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

9.43 not clear if this includes whether assigned to placebo or active drug

9.9 states every change to ICF to be reviewed, not consistent with HDEC SOPs non-substantial amendments 9.26 grammar: "at a different times" --> "at different times"

and "as well as being identifying conflict" --> "as well as identifying conflict"

Does 9.16 imply that can not complete demographic page (name, contact details etc) when arrive, to be completed after consent? Or is this referring to medical history questions etc?

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft**

**standards provide clarity for the regulatory and ethical environment? NEAC notes that they**

**can revisit the ethical advice if the law changes: Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

### Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

12.4 refers to 'therapeutic intervention', 12.5 and 12.6 just 'intervention', but should they say 'therapeutic' too?

### Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

13.27 for advert 'avoid eye-catching visual cues' – what would these be? An advert that's only text is unlikely to fulfil it's purpose as an advert to garner interest.

Table 3 – don't understand. Is Randomised trial in setting 2 (not life threatening disease etc) 'Unlikely' to have Ethical Integrity or 'Unlikely' to have Ethical Integrity issues?? – either way, neither seems right.

**Charging participants**

**Please outline your reasons:**

**Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

14.37 typo: 5esearchers --> Researchers

14.17, 14.39, 14.40 - (as noted in general answers) For clinical trials with investigational medicine it is important to balance risk to privacy with risk to safety – dangerous to remove personal identifiers to protect participant privacy if it results in wrong medication being administered or being unable to identify correct records in the event of a medical emergency.

Records kept identified in archive for the same reasons, to be able to contact participants if safety information found further down the track.

**Big data and new ways of using data**

Not Answered

**Please provide feedback:**

Response number	43
Name	[redacted]
Organisation	[redacted]
Role	Professor
Researcher	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable

Agree

**Please outline your reasons:**

The standards are applicable to all types of health and disability research

Disagree

**Please outline your reasons:**

I agree that the standards could be applicable to all types of health and disability research with some minor amendments. However, the standards as currently defined do not appear to have considered public health intervention research, where clinical trials may be used to evaluate interventions in groups other than patients, but rather seems to be grounded in the implicit view that either [1] it is not necessary for HDECs to evaluate research that recruits health people without disease or clinical conditions, or [2] has ignored the fact that public health trials are being conducted.

The standards balance protecting individuals with the realities of conducting research

Neutral

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research

Agree

**Please outline your reasons:**

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:**

Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### Coverage of ethical guidance

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

Mostly, with reservations outlined elsewhere in this submission.

### Merging the observational and interventional guidelines

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

Agree, but with the reservations outlined elsewhere in this submission.

### Scope of the standards and non-research activities

**Is the scope of the document clear?**

Strongly Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

Paragraph 4.6: It is reassuring to see that generally audit and quality improvement are not considered non-research activities even if clinical records are accessed and/or publication of general findings is an intended element of the project. I strongly support this position.

### Ethical principles

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

I support the inclusion and alignment of Te Ara Tika and Bioethics principles in the framework. It is a very useful outline to promote understanding and respect for role of Te Tiriti O Waitangi within the research community.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

I particularly support paragraphs 8.13 and 8.14 as vulnerable groups have a right to participate in research, although that may require researchers to take extra measures in designing their research. Ethics committees similarly need to consider that vulnerable groups still receive treatment and deserve to have treatments that have been evaluated in populations similar to themselves.

### Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Paragraphs 11.15 to 11.17 refer to equal explanatory power. I support the inclusion of paragraphs 11.15 and 11.16, but 11.17 could be problematic if it is interpreted as requiring all studies to have equal explanatory power. It is certainly important that studies should have equal explanatory power where that is consistent with the study hypotheses. However, where the demonstration of equivalent effects in different populations is not relevant to the study hypothesis (or hypotheses), then there is the potential that ethics committees may over-reach in their judgements if they reject studies because they have not sought to either investigate or to demonstrate equal explanatory power. I recommend that the document provide clearer guidance as to the scope of paragraph 11.17

### Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Disagree

**Please outline any missing ethical issues or principles:**

There is no discussion of cross-over trials or of n-of-1 RCTs, which are a specialised form of cross-over trial. Both of these designs have been used in New Zealand and guidance on any issues needs to be provided to ethics committees ie that the design is only appropriate for clinical conditions that can be palliated (eg arthritic pain), but not for conditions that can be cured (eg acute skin infections). Other issues such as number of cross-overs and wash out period need consideration. Further there is no discussion of issues regarding equivalence or non-inferiority trials (particularly the use of appropriate active comparisons, rather than inappropriate comparisons such as reduced dose comparisons).

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Paragraph 12.13 is written as if the only types of trials are parallel group designs where participants are allocated to one treatment. However, it could be written so that it also includes the various cross-over designs ie "Such a trial allocates participants to the intervention arms or order of treatment in a way that minimises the influence of confounding factors ...".

Paragraph 12.14 includes sample size as an example of a design element that contributes to bias or systematic error. In fact, sample size does not manage bias, but manages to random error. The



paragraph should remove this element from examples of bias. It would probably be useful if the document could state sample sizes manages random error in trials and generally trials should include an a priori specified sample size calculation with all the assumptions exposed. However, there are some cases where an a priori sample size calculation may not be necessary, such as in feasibility studies or pilot trials, which are testing feasibility issues and perhaps collecting information for a sample size calculation for larger trial. Another example where an a priori sample size calculation may not be initially feasible is in adaptive sequential trials where estimation or re-estimation of the sample size occurs during the course of the trial

Paragraph 12.15 simply outlines what are potential harms in trials. Still to be published methodological research I have conducted shows that only about 54% of the published trials in my field (treatment of venous leg ulcers) since 2001 have any form of adverse event reporting ie all-cause or disease-specific adverse events. Thus large numbers of trials in my field are not reporting adverse events, a finding that is consistent with data in other fields. I would recommend the inclusion of a statement at the beginning of paragraph 12.15 that all trials of interventions for clinical conditions must include data collection and reporting of adverse events. The CONSORT statement 2001 on reporting of trials recommended that trials at least report important adverse events.

While paragraph 12.29 starts with an accurate description of the approach, the paragraph ending and the beginning of paragraph 12.30 seem unnecessarily suspicious of co-design approaches when these approaches have the considerable advantage of citizen control to research design. There is no particular problem with the co-design approach that cannot be overcome with staged or phased applications.

Paragraph 12.41 uses the term comparative effectiveness research. This term is quite unusual and is probably better substituted for head-to-head and/or pragmatic trials depending on the actual intended meaning.

## Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Paragraph 13.12 states researchers should register their studies. The language here is not sufficiently strong as it allows exceptions and lacks clarity as not all studies are randomised controlled trials, which are the target for trial registration, whereas observational studies do not need to be registered. The International Committee of Medical Journal Editors and the Surgical Journal Editors Committee have both stated that all trials need to be prospectively registered on

public domain WHO-compliant clinical trials registers. It is still possible to register trials on non-compliant registers. Therefore, for the sake of clarity, I recommend [1] that the language be strengthened and [2] the terms randomised controlled trial and WHO-compliant trials register be used. Hence I request the document be changed to read "Researchers must register their randomised controlled trial in a WHO-compliant clinical trials register."

Paragraph 13.45 states every study requires a safety monitoring plan. Again the use of the term study is potentially confusing here, as observational studies are unlikely to require a safety monitoring plan. Similarly, upstream public health interventions (such as information provision to improve healthy eating) and cluster randomised controlled trials may not require a safety monitoring plan. However, it seems likely that all trials involving participants with a clinical condition will need a safety monitoring plan. Other kinds of trials not using patients as participants may also need safety monitoring ie use of caffeine in shift workers if this document is to apply as a standard for all types of human participant ethics committees in New Zealand and not just HDECs. Thus the paragraph needs to be revised to address [1] the possibility that there are some categories of trials that do not need a safety monitoring plan and [2] the possibility that the standards need to consider the categories of trials not covered by HDECs but having the potential to be considered by university human participants committees.

Paragraph 13.48 ends by stating that DMC members should have prior DMC experience, especially the Chair and the statistician. While I agree there should be at least some prior experience present on a DMC, to expect the statistician to always have had such experience means that the standard supports a version of sundowning in this occupation - one cannot become experienced without starting at a beginning somewhere. The paragraph needs to be revised to acknowledge career growth and allow for statisticians for be beginners.

### Charging participants

#### **Please outline your reasons:**

I do not support for clinical trial participation in any circumstances.

### Databanks

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

#### **Please outline your reasons why the section is or is not fit for purpose:**

Databanks are not the only vehicle for data sharing. It may that data in total or in part could be requested by international researchers for specific circumstances, such as an individual participant data meta-analysis. This section needs to incorporate such examples into the section and perhaps retitle the section along the lines of "Data banking and other data sharing approaches for secondary use of original data".

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

#### **Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Paragraph 14.22 uses the term "identifiable data", which suggests appears that consent is only required when "identifiable data" as defined in paragraph 14.35 is to be sent overseas. If that is the case then a standard or guidance also needs to be provided on data sharing "re-identifiable data". For instance, is it the current position that "re-identifiable data" that is data banked in non-New Zealand databanks or shared for purposes like individual participant data meta-analyses by international researchers does not require -re-consenting? I would support an approach that involves either [1] not having to apply for an ethics committee waiver or [2] only having to apply for a ethics committee waiver where re-identifiable data is being shared for secondary research. Such an approach means that all data can be used to answer questions in individual participant data meta-analyses and methodological research; if data sharing is limited to providing data where consent has been obtained to send re-identifiable data overseas, then many older studies could not provide their data to help answer clinical questions and thus summaries of evidence will be incomplete. Incomplete evidence summaries are useful to neither researchers nor patients.

It is a minor concern, but paragraph 14.23 does not outline whether the three indications for obtaining consent are mutually exclusive (linked by "OR") or are cumulative (linked by "AND"). I presume the in Committee's intention is the former rather than the later, but the document must be clear about the intent. I recommend that the document be revised to ensure that three indications for obtaining consent for data re-use in an original study are treated as mutually exclusive categories and linked by "or" at the end of each sentence for the first two indications.

**Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

Response number	44
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher, genetics
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

Over the last 10 years there have been rapid advances in human research technologies and dramatic changes in the focus of questions that researchers ask. These advances and focus changes, along with publication in 2016 of consolidated guidelines outlining expectations of Māori for both genomics and tissue-based research, and publication in 2017 of the NZ Health Research Strategy, make a review of the 2012 Ethical Guidelines for Intervention and Observational Studies timely, if not overdue.

A set of standards targeted at individual researcher responsibility (rather than a set of guidelines) seems very appropriate, especially as public expectations of research increase and the regulatory environment is strengthened.

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

While I agree with this statement, I think there may be two issues that need to be addressed as the standards are implemented. Please also see response to question 7, below:

- 1) In my view it is important to even more clearly define what research is.
- 2) I understand anecdotally (but have no evidence) that there may be a degree of geographical, temporal, and ethics committee-to-ethics committee inconsistency in interpretation the 2012 Guidelines. How will consistency between committees when applying these standards be monitored and supported, especially in the difficult area of determining what is in scope / what is research?

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research

Agree

**Please outline your reasons:**

These standards targeted at individual researchers. However, from both a legal and reputational perspective, I imagine these standards will place an indirect monitoring and compliance responsibility on organisations employing researchers such as CRIs, universities and DHBs?

Resources may need to found within these organisations to carry out these monitoring and compliance roles, and linked to this support and education, over and above the significant ethical work they already do, which would be a positive advance.

Will these standards be accompanied by detailed information and frequently updated educational materials (including discussions of common difficult scenarios) that support both individual researchers and institutions to uphold the 2018 Standards?

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Neutral

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Neutral

**Standards - protect and reassure the community:**

Neutral

**Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Neutral

**Please describe the ethical challenges that are missing:**

As I noted below, even though it is addressed by the standards, I personally think there is one area that requires additional focus and clarity, "grey area" clinical studies that really are research being misunderstood as clinical testing.

**Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Neutral

**Please outline your reasons:**

### Scope of the standards and non-research activities

**Is the scope of the document clear?**

Neutral

**Please outline your reasons or suggested improvements:**

In my personal view, the boxes describing research (Section 4.3) and non-research (Section 4.6) require additional consultation and then some expansion. A particular example where I see misunderstanding currently occurring is clinical genomics, where studies that really are research by the definition in the box in Section 4.3 are sometimes misunderstood as clinical testing. Bearing this example in mind, while I understand why the standards have taken the view that “how to determine what an activity is has not been included” I suspect this will leave committees and researchers to make their difficult decisions which may not be informed or nationally consistent. Therefore, as individual HDEC and Institutional ethics committees work through this type of issue project-by-project, can a mechanism be established to consolidate the “case law” that is progressively generated by each committee into a well-organised and frequently updated database that committees can refer to, and then contribute to, as they make approval decisions?

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### Ethical principles

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Research involving Māori

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?

Neutral

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Great to see precognition of the potential value of new consenting technologies.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback**

NoResearch with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes: Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

### **Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Very helpful explanation.

Links to additional educational resources to ethical principles that may help researchers take personal responsibility may be helpful.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback**

No

**Please provide feedback with reference to the paragraph(s) in question:**



## Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

## Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback**

No

## Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Charging participants**

**Please outline your reasons:**

### **Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Big data and new ways of using data**

Agree

**Please provide feedback:**

Formal data management plans and repeatable/reusable research strategies are becoming the norm and should always involve ethical considerations.

### **Databanks**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback**

No

### **Human tissue**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The risks and benefits of tissue-based research sit as much with the data generated from the tissue as with the tissue itself, of course. This data is sometimes only loosely controlled by researchers, as noted in the Standards.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Biobanks

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

National collaboration of biobanks is a current issue that may need addressing. Playing Devil's advocate - Is it ethical to collect tissue for Future Unspecified Research that is never used simply due to researchers being unaware of tissue resources around NZ, or the ability to assemble study cohorts of tissues from multiple NZ tissue banks? Is there a responsibility to assemble nationally connected databases of tissue held by NZ's various tissue banks?

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Research with stem cells

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

This is an area that will require frequent updating, and needs to align with ERMA guidelines.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

**Compensation for commercially sponsored intervention studies**  
The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Response number	46
Name	[redacted]
Organisation	[redacted]
Role	Principal Researcher
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Strongly Agree

#### Please outline your reasons:

This is a really comprehensive document. It covers a much wider range of research types than the previous standards and is much more in keeping with the range of research currently being undertaken in Aotearoa New Zealand. The inclusion of a chapters on Research involving Maori and Pacific peoples is welcomed.

The standards are applicable to all types of health and disability research  
Strongly Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Strongly Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Strongly Agree

#### Please outline your reasons:

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Strongly Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Strongly Agree

**Standards - reflect the principles of the Treaty of Waitangi:**  
Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Strongly Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Strongly Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Strongly Agree

**Standards - protect and reassure the community:**

Strongly Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Strongly Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

This represents a very rational change - much preferred to two separate documents.

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Strongly Agree

**Please outline your reasons or suggested improvements:**

The inclusion of a table of activities regarded as 'non-research' is very helpful.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Strongly Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

This chapter gives much needed guidance on consultation with Maori. An issue arises with the requirement to engage with Maori "who have sufficient knowledge to play a meaningful role'. These individuals are rare and it can be very difficult to identify Maori to partner with. Those individuals who make themselves available are over-worked and often not reimbursed for their time or contribution to the research process. The same applies to work involving Pacific peoples. Consideration should be given to facilitating this process, for example, by identifying a group of individuals who are prepared to undertake this work and would be available to researchers from host institutions that do not provide adequate resource. The consultants could be paid in a similar manner to HDEC committee members.

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Very comprehensive.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research with participants who are unable to consent**

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

YES - the draft standards provide clarity. As outlined in section 9.67 and 9.68, there are good reasons for research to be undertaken in this group of patients. Indeed, it is not ethical to exclude



individuals from participation in health and disability research just because they are unable to give consent. Research in the emergency and intensive care environment has potential to improve care for cohorts that follow - it is vital that the research is allowed to proceed.

### Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

The guidance given is appropriate.

### Research benefits and harms

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Charging participants**

**Please outline your reasons:**

The guidance is prohibitive. An important issue relates to why the research has not found other funding options. If the work has been peer-reviewed and significant concerns have been raised about the likelihood of the work providing a clear answer to the research questions, one could argue that it should not proceed.

### **Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Big data and new ways of using data

Strongly

**Please provide feedback:**

### **Databanks**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Human tissue**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Biobanks**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research with stem cells**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Strongly

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Response number	47
Name	[redacted]
Organisation	[redacted]
Role	Member of the Mātauranga Māori Komiti
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

The standards are applicable to all types of health and disability research  
Strongly Disagree

#### Please outline your reasons:

Point 1.2 in the introduction to the standards states that research “has the potential to generate knowledge and methods that can protect and promote the health and independence of individuals, the population and groups within that population”. However, independence is a western concept grounded in individualism. In contrast, Māori people put emphasis on self-determination (tino rangatiratanga). We respectfully submit that the standards address the health goals articulated by the World Health Organization, which are, simply, inclusion and participation.

The standards balance protecting individuals with the realities of conducting research

Neutral

#### Please outline your reasons:

This question privileges western individualism. More importantly, the standards need to respect Māori cultural values and protect Māori people as tangata whenua by giving those values equal standing alongside bioethical principles to shape the design and conduct of research. As outlined throughout our submission, this message needs to be strengthened.

The standards support researchers to navigate ethical challenges in health research

Strongly Agree

#### Please outline your reasons:

Bioethical principles and concepts of privacy have dominated ethical considerations. The draft standards support researchers to design research that is primarily driven by Te Ara Tika principles, which opens possibilities for culturally responsive recruitment and consent processes, and incorporation of tikanga Māori protocols to address cultural safety of researchers and participants.

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:**

Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Disagree

**Please outline your reasons or suggested improvements:**

The standards “set out the established ethical standards that apply to all health and disability research in New Zealand” (p. 1) and explicitly acknowledge the Treaty of Waitangi as making the Crown and Māori equal partners in co-governance. To actualise that message throughout the document, we strongly urge adoption of “Aotearoa New Zealand” when identifying the context of development and application of the standards.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

We applaud presentation of Te Ara Tika principles ahead of bioethical principles. This sends a strong and necessary message to researchers and research funders.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

The standards support later statements about overcoming health inequities.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Manaaakitanga

This section specifies “the importance of collective participation in establishing the goals and benefits of a research proposal, and empowering research partnerships”. Upholding the mana of Māori people starts long before considering the goals/benefits of a specific research proposal. It begins with determining the research agenda, knowledge generation priorities and allocation of funding. We suggest an alternate wording:

“... the importance of collective participation in setting the research agenda, funding priorities, establishing the goals and benefits of specific research proposals, and empowering research partnerships”.

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

The title of the section legitimizes the idea that some research does not involve Māori. Perhaps it is intended to particularly address studies that recruit Māori participants or analyse Māori health data, but if that is the intention, Standard 6.7 (Researchers must collect ethnicity data) is misplaced as it is intended to apply to all research.

6.2 The rights of indigenous people in New Zealand, or tangata whenua, are the rights to:

... policy based on evidence that is valid for Māori.

Evidence is always generated from a particular world-view / research paradigm. Policy must be based on research consistent with a Māori world view. We suggest the following revision:

... policy based on evidence that is consistent with Māoritanga and valid for Māori .

### Standard 6.3

The term cultural rigour is introduced but not defined. In the Auckland consultation meeting, it was described as signalling that Māori ethics are elevated to the same level as bioethics – but that message is obscured if the term is not clearly defined.

### Standard 6.7

We particularly endorse the requirement for all researchers to collect ethnicity data.

The importance of health research with Māori

6.9 There are significant inequalities in health status .... etc.

This commentary explains health inequalities in terms of access to determinants of good health, access to health and disability services, and the quality of care received. This account of Māori health status is seriously deficient in not acknowledging the impact of colonisation. We strongly assert the need to begin this account with an additional bullet point to the effect that:

- Inequitable consequences of colonisation, where Māori were subjected to dispossession of their land, appropriation of resources, alienation from their culture, and disruption of traditional relationships, responsibilities and practices

### Consultation 6.18

While matters of culture are important in the research process, researchers also need to consider conceptual issues and questions, along with the shape of research outputs. In this way, the results from health research can contribute more strongly to the health status of Māori.

Acknowledging that what is good for Māori is good for all New Zealanders, we recommend extending the final statement to read:

In this way, the results from health research can contribute more strongly to the health status of Māori and benefit all New Zealanders.

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Strongly Disagree

**Please provide feedback with reference to the paragraph(s) in question. :**

6.12 Consultation is expected for all health research.

This commentary concedes that “in practice researchers often conduct it after they have set their research protocols”. In effect, this concession endorses continuation of the status quo. Clearly that is not good enough. We recommend in the strongest terms that this sentence is deleted. Further, that the following sentence, which currently reads:



“Engagement with Māori at an early stage in the design of the study is preferred, particularly for research involving Māori. “ (p. 21) Is revised to read:

Engagement with Māori at an early stage of determining the research question, prior to designing the study is preferred, particularly for research involving Māori.

Response number	48
Name	[redacted]
Organisation	[redacted]
Role	Senior Consultant
Interest group	consultant and adviser to researchers and institutions on principles and practice of human research ethics and research integrity
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

Preface

We offer the following comments in a spirit of supportive collaboration. As Australians, we recognise and acknowledge that we lack sufficient experience and familiarity with the Treaty of Waitangi and with Maori and Pacific peoples.

We deeply respect these fundamental considerations that underpin these standards and have read, with enlightenment, sections 2, 6 and 7 which deals specifically with them. As an expression of that respect, we have not sought to comment on the interpretation, understanding and application of those sections where these considerations are central.

However, we have extensive experience in the development, interpretation and application of principles and standards relating to the conduct of human research. We have been directly involved in the drafting and revision of all of the iterations of the Australian National Statement on Ethical Conduct in Human Research, from 1999 to 2007 and most recently in 2018.

This experience does give us some insight into the broader considerations that affect the preparation of such standards, particularly with regard to the precision and consistency with which, in our experience, are necessary in their expression. Although we agree with the intent to provide a document that operates as a broad set of standards, in our experience, it is unavoidable that the document will be given a literal application. Where that interpretation exposes any inconsistencies, internal contradictions or uncertainty in meaning, in our experience, these are likely to weaken the authority and acceptance of the standards.

Our experience suggests further that such consistency is necessary not only within any one chapter but throughout the document.

Accordingly, our comments will identify examples of such occurrences that in our view merit further consideration.

There are some areas of research covered by these comprehensive standards in which we lack the necessary scientific expertise, and we have accordingly decided not to offer comments in these areas.

It is on these premises that we offer the following comments.

### Structure and use of the Standards

Our experience strongly suggests that clarity as to status of paragraphs is centrally important to their consistent and constructive use and to their acceptance by researchers, reviewers and institutions. This is particularly important to developing collaborative relationships among ethics committees and researchers and to their respective use of the standards to support and explain the sometimes different positions they take on projects submitted for review and to the harmonious resolution of those differences.

With these consideration in mind, we note the distinction (paragraphs 3.2 & 3.3) between Standards and Commentary and the recurrence of these headings in succeeding chapters. We also note the guidance about the use of the terms “should” and “must” in paragraph 3.21.

We question whether the frequent use of “must” in paragraphs of Commentary throughout the document confuses the intended difference between Standards and Commentary. The use of that term appears to grant Standards and Commentary paragraphs equal weight in reasons for decisions by ethics committees and in arguments made by researchers in support of their view of a study.

We consider that further consideration be given to the use of the terms Standards and Commentary and to an explanation of their relative weight. We notice that among the references is the Canadian Tri-Council Policy Statement, a document that makes and maintains a clear distinction between articles and commentary. It is the best known example of such a structure and, while we do not recommend wholesale adoption of that structure, we do suggest that the clarity and consistency of its structure is instructive.

**The standards are applicable to all types of health and disability research**  
Agree

### **Please outline your reasons:**

Scope of the standards - Chapter four

Paragraph 4.3 contains a box which seeks to define the scope of the standards has both a general definitional passage and a more specific paragraph of definitions.

We suggest that the more specific paragraph be reviewed to ensure that it is confined by the concept of health and disability research. At present, the literal language of that paragraph has no such limitation. We understand that such a limitation may reasonably be expected to be implied from the context of the document as a whole, but in our experience, it is prudent to rely on explicit rather than implicit interpretations.

Paragraphs 4.5 and 4.6 attract a similar observation. Making paragraph 4.5 explicit to health and disability research, and not only health research, would improve clarity.

In our view, the advice given in paragraph 4.6 as to the application of the standards to non-research practices might be improved if the similarities between those activities and research focused on the involvement of human participants rather than the more general "share features of research". In our view it is the involvement of humans in these activities that attracts the need for their ethical conduct.

We read with admiration paragraphs 4.7 to 4.22. This is an excellent account of the difficulties of providing realistically applicable advice on the ethical conduct of innovation in health care.

The standards balance protecting individuals with the realities of conducting research

Agree

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research

Agree

**Please outline your reasons:**

Chapter 5 Ethical principles

Paragraph 5.3 and "the bioethics principles"

It is here that we respectfully differ with a fundamental component of the standards. In our view, the adoption of the established formulation and meaning of what are referred to as the bioethics principles, namely, respect for people, beneficence, non-maleficence, and justice fails to adapt these familiar ideas to the human research context.

Originally formulated by Robert Beauchamp and James Childress in their 1969 "Principles of Biomedical Ethics", the primary application of these principles was clearly to the clinical context of healthcare. Although the authors recognised the potential application in other contexts, the meanings given to them in the standards are closer to those originally devised and, in our view in important aspects can be misleading.

The reason for this is the difference between the ethical responsibilities of clinicians to patients from ethical responsibilities of researchers to research participants.

The primary ethical obligation of a clinician is to the welfare of her patient and this gives to the meanings of beneficence and nonmaleficence very clear and well-established meanings.

Researchers have ethical obligations to the welfare of participants in research for which they are responsible but that obligation cannot have the same primary position as for clinicians. This is because an equally important goal of researchers is the realisation of the aims of the research project, a commitment that must be balanced with, rather than the subsidiary to their ethical obligation to the welfare of research participants.

Accordingly, in our view, the meaning of beneficence in a human research context is closer to what Beauchamp and Childress described as the principle of utility, that is, that any harm to research participants could only be ethically acceptable if it was justified by the likely benefits of the research. We acknowledge that this point is made in the account of nonmaleficence but suggest that the first two sentences of that account are contradictory: both, as written, cannot be true. It is the nature of research that participants and indeed communities may be exposed to risks of harm so that the central obligation in this regard for researchers is to minimise those and to justify any that remain likely.

In our view, this central difference between the bioethical principles as originally devised for clinical practice and their application in human research should be made clearer than it presently is. In our view, for these reasons, it would be prudent to revisit their expression and whether the inclusion of nonmaleficence is necessary.

The principle of research merit

In our view, a centrally important ethical principle is that human research have research merit and that researchers conduct the research with integrity. In their seminal article, Emmanuel and colleagues reviewed 12 international statements of human research ethics and extracted seven consistently recurring requirements for the ethical conduct of human research. The first and second of these were that, for research to be ethically acceptable, it must have value and scientific validity.

We recognise that this matter is introduced and discussed thoroughly and practically in Chapter 11 of the Standards.

However, we remain of the firm view that this requirement is as important as any of those in the bioethics principles and so merits recognition at the same fundamental level at the commencement of the standards.

### **Overall do the Standards?**

#### **Standards - safeguard the rights and interests of participants in research:**

Agree

#### **Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

#### **Standards - reflect the principles of the Treaty of Waitangi:**

Strongly Agree

#### **Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

#### **Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Neutral

#### **Standards - help researchers give due consideration to local and national community views and perspectives:**

Neutral

#### **Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

#### **Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

#### **Please outline your reasons:**

## Scope of the standards and non-research activities

Is the scope of the document clear?

Neutral

**Please outline your reasons or suggested improvements:**

Scope of the standards - Chapter four

Paragraph 4.3 contains a box which seeks to define the scope of the standards has both a general definitional passage and a more specific paragraph of definitions.

We suggest that the more specific paragraph be reviewed to ensure that it is confined by the concept of health and disability research. At present, the literal language of that paragraph has no such limitation. We understand that such a limitation may reasonably be expected to be implied from the context of the document as a whole, but in our experience, it is prudent to rely on explicit rather than implicit interpretations.

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In our view, the advice given in paragraph 4.6 as to the application of the standards to nonresearch practices might be improved if the similarities between those activities and research focused on the involvement of human participants rather than the more general "share features of research". In our view it is the involvement of humans in these activities that attracts the need for their ethical conduct.

We read with admiration paragraphs 4.7 to 4.22. This is an excellent account of the difficulties of providing realistically applicable advice on the ethical conduct of innovation in health care.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question.** : see reasons for the answer to the previous question

## Ethical principles

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

Chapter 5 Ethical principles

Paragraph 5.3 and "the bioethics principles"

It is here that we respectfully differ with a fundamental component of the standards. In our view, the adoption of the established formulation and meaning of what are referred to as the bioethics principles, namely, respect for people, beneficence, non-maleficence, and justice fails to adapt these familiar ideas to the human research context.

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meanings given to them in the standards are closer to those originally devised and, in our view in important aspects can be misleading.

The reason for this is the difference between the ethical responsibilities of clinicians to patients from ethical responsibilities of researchers to research participants.

The primary ethical obligation of a clinician is to the welfare of her patient and this gives to the meanings of beneficence and nonmaleficence very clear and well-established meanings.

Researchers have ethical obligations to the welfare of participants in research for which they are responsible but that obligation cannot have the same primary position as for clinicians. This is because an equally important goal of researchers is the realisation of the aims of the research project, a commitment that must be balanced with, rather than the subsidiary to their ethical obligation to the welfare of research participants.

Accordingly, in our view, the meaning of beneficence in a human research context is closer to what Beauchamp and Childress described as the principle of utility, that is, that any harm to research participants could only be ethically acceptable if it was justified by the likely benefits of the research. We acknowledge that this point is made in the account of nonmaleficence but suggest that the first two sentences of that account are contradictory: both, as written, cannot be true. It is the nature of research that participants and indeed communities may be exposed to risks of harm so that the central obligation in this regard for researchers is to minimise those and to justify any that remain likely.

In our view, this central difference between the bioethical principles as originally devised for clinical practice and their application in human research should be made clearer than it presently is. In our view, for these reasons, it would be prudent to revisit their expression and whether the inclusion of nonmaleficence is necessary.

The principle of research merit

In our view, a centrally important ethical principle is that human research have research merit and that researchers conduct the research with integrity. In their seminal article, Emmanuel and colleagues reviewed 12 international statements of human research ethics and extracted seven consistently recurring requirements for the ethical conduct of human research. The first and second of these were that, for research to be ethically acceptable, it must have value and scientific validity.

We recognise that this matter is introduced and discussed thoroughly and practically in Chapter 11 of the Standards.

However, we remain of the firm view that this requirement is as important as any of those in the bioethics principles and so merits recognition at the same fundamental level at the commencement of the standards.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:** see reasons for first answer and comments on paragraph 5.3

### Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:** Chapter 8 Categories of Participants

We compliment the committee on adopting the structure used in this chapter and of the use of vulnerability as an underlying characteristic that is expressed in a wide range of circumstances, all of which are carefully and thoughtfully explained. Although we read the whole chapter with increasing admiration, there were some specific matters of comment, being examples of an earlier observation about the importance of consistency and clarity in terminology.

Given that vulnerability is clearly recognised as context-specific, the use of the term “potentially vulnerable” may need further explanation. Every potential research participant could accurately be described as potentially vulnerable because the source of that vulnerability will lie in the research context. If this is the case, we question whether “potentially vulnerable” is a useful term and may be replaced by a short prelude to the fact that vulnerability in research is context specific, as ably explained in succeeding parts of Chapter 8.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

We question the wisdom of apparently using the terms “capacity” and ‘competence’ interchangeably, as is done in paragraph 8.15, as our understanding is that these terms have distinctly different meanings. In our view, the better term is capacity because we understand that it refers to a capacity to make a given choice at a specific time and in a specific context.

We also question the wisdom of the last sentence in paragraph 8.30, although we do understand that the context could be relied on to explain the intended meaning. However, our experience indicates that reliance on such implication can lead to ambiguity and uncertainty that can affect the acceptance of standards such as these. As a result, we would counsel against using absolute sentences such as this lest they be taken literally.

### Informed consent

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral



**Please outline your reasons why the section is or is not fit for purpose:**

Chapter 9 Informed Consent

As before, we compliment the committee on their thorough and perceptive treatment of this subject. We recognise that the expression “informed consent” aptly recognises the use of that expression in the clinical context in New Zealand.

Our comment is that care needs to be taken that such familiarity with the clinical context does not overlook the other necessary components of an ethically sound consent to research. Unlike the clinical context, the main aim of what is being consented to in research is not necessarily the welfare of the consenting participant.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:** see reasons for the answer to the first question

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

The parenthetical reference to writing in Paragraph 9.2 is, in our view, unnecessary and could be the kind of language relied on to privilege that mode of expressing consent. In our view, nothing would be lost, and much gained, by omitting those words and relying on the excellent later accounts of alternative modes of expressing and evidencing consent in paragraphs 9.18 – 9.23.

Paragraph 9.4 is an early example of a practice we strongly endorse and encourage more of: that is, in specific paragraphs, referring to the underlying relevant principles. With that in mind, we wondered why the opportunity was not taken to refer to the relevant bioethics principle, as well as the relevant Maori principle.

Paragraphs 9.7 and 9.29 provide further examples of the risk, in our view, of using apparently absolute expressions for situations that will always be contingent. The requirement in these paragraphs that participants must receive and that researchers must disclose “all information” relevant to a participant’s decision to participate risks being the basis of unnecessary and burdensome disclosure, of the kind that is dissuaded in paragraph 9.31. We would recommend a less absolute expression.

We note in passing and question why the term “vulnerable” is framed with quotation marks in paragraphs 9.23, given the thorough and clear account of the term in chapter 8.

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

not answered

Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

Consideration may need to be given to ensuring that paragraphs 9.27, which appears to prohibit deception, is clearly consistent with paragraphs 9.42 - 9.46

## Research benefits and harms

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

### Please outline your reasons why the section is or is not fit for purpose:

Chapter 10 Research benefits and harms

Paragraph 10.1 contains another example of an apparently absolute proposition, namely, that all research carries some risks of harm. In our experience, a modification to “most” could avoid pedantic criticism but make the same ethical point.

The comparison between the harms and benefits of research is often characterised in terms of comparative weight, as here. However, in our view, because this is an essentially ethical judgment, rather than a comparative weighting, our suggestion is to consider using the expression “justified”, i.e. that any potential harms are acceptable only if they are justified by the potential benefits of the research.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

### Please outline any missing ethical issues or principles:

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

### Please provide feedback with reference to the paragraph(s) in question:

In paragraph 10.07, we would encourage expanding the concept of welfare and independence to include health and dignity.

In paragraph 10.12, we would encourage consideration of adding to the examples of autonomy harms those of loss of agency or opportunity for self-determination.

We note that paragraph 10.13 identifies therapeutic and non-therapeutic benefits and harms. In our view, this classification may be confusing because it particularises the classification once made in earlier versions of the Declaration of Helsinki between therapeutic and non-therapeutic research, but which has not been used in more recent versions. We suggest reconsideration of whether this classification adds to an understanding of a consistent focus on the identification and minimisation of risks of harm in research and justification of those that remain by reference to the potential benefits of the research.

The concept of minimal risk has proved difficult to define and we appreciate the refinement of a common definition in paragraph 10.14 so that an assessment is related to the experience of participants in a specific research project. However, the implications of this are that what is acceptable as minimal risk can vary widely according to the characteristics of particular participants and of particular projects. This will probably affect the risk classification of projects and hence their ethics review pathways and could lead to considerable uncertainty for researchers and institutions.

We encourage further consideration of this approach in favour of a simpler definition that is more likely to generate a common risk standard for any project.

The discussion in paragraph 10.19 of the fair distribution of risks and benefits of research appears to carry an assumption that all research has a population wide application, as it focusses on representation of groups. We encourage further consideration of providing for research projects that are justifiably focussed on sub-groups of populations and whose risks and benefits would not extend to whole populations.

### **Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Chapter 13 Research Conduct

Our Australian experience of the imposition of privacy regulation on the use of patient information for research exposed the same issue as is addressed in paragraph 13.21. There was considerable debate as to whether such practices were a “use” of health information that required patient consent. For this reason, we raise the question of whether these practices are within New Zealand privacy regulation.

Paragraph 13.24 raises, we suggest, another example of the importance of clarity and consistency. We understand and support the apparent objective here of seeking to achieve the optimal introduction of research to potential participants. However, read literally, the first two sentences in this paragraph are likely to be inconsistent in any situation where those involved in a patient’s care have no prior knowledge of or involvement in proposed research.

Paragraph 13.79 alerts researchers to the importance of planning for how to deal with test results and incidental findings. Our comment is that the location of this sound advice at a place in the standards that addresses the course of conduct of research rather than the planning of research may fail to most effectively alert researchers to the need to embed these matters in planning research.

Charging participants

**Please outline your reasons:** no comment offered

## Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:** Chapter 14 Health Data

We recognise that an adequate understanding of New Zealand privacy law and of relevant Maori standards is a necessary foundation for informed comments on this chapter. Lacking this knowledge, we have not commented on the chapter, other than to note the following example of the general observation about document wide consistency.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Paragraph 14.7 provides another example of the risk that apparently absolute statements can present to standard-wide consistency.

Our comment is whether this sentence is consistent with paragraph 9.65, which recognises that researchers may be able to justify accessing and using patient identified data for research without patient consent.

Big data and new ways of using data

Neutral

**Please provide feedback:**

Response number	49
Name	[redacted]
Organisation	[redacted]
Role	Chief Data Officer
Interest group	Government agency
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

The standards are applicable to all types of health and disability research  
Neutral

#### Please outline your reasons:

Clarification of where the line between Quality Improvement and Research is could be better, and done including examples.

The standards balance protecting individuals with the realities of conducting research  
Disagree

#### Please outline your reasons:

Largely yes, however I believe there is case for 'trusted' organisations to have broader access to health (outcomes) data and use this much more frequently to inform quality improvement, service planning and healthcare value based decision making by the health funder.

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Neutral

**Standards - reflect the principles of the Treaty of Waitangi:** Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Disagree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Neutral

**Standards - help researchers give due consideration to local and national community views and perspectives:** Neutral

**Standards - protect and reassure the community:**

Agree

### Coverage of ethical guidance

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### Merging the observational and interventional guidelines

The standards are applicable to both observational and interventional research

Neutral

**Please outline your reasons:**

Standards are applicable to both, however the purposes should be clearly separated:

1) observational, after the fact, retrospective = low risk, low requirement for patient consent, high threshold for ethics/privacy concerns. 2) interventional, during treatment = higher risk, requires higher level of consent from participant and/or ethics approval

### Scope of the standards and non-research activities

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

By its nature, research will not always identify what data is required beforehand. therefore, expecting research to be limited to using only the data for which patient consent was obtained beforehand. (14.23)

Accessing other data should be possible, as long as patient has consented to broad research purpose up front.

It is not practical to exclude data for specific patients from analysis. (14.18)

14.20 is not practical as not all patient data has defined ethnicity.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

Big data and new ways of using data

Disagree

**Please provide feedback:**

See comments earlier.

the nature of Big Data is that data from multiple sources is linked, and requires identification to do so. the linking needs to be retained in order to be meaningful for a research purpose that is not yet defined in the future. The linked data needs to be open for research purposes that are defined by algorithms, driven by a higher level goal.

## Databanks

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

Access and linking of relevant databanks for research and more quality improvement needs to become easier.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

14.58



Data governance over databanks needs to balance the needs from the consumer with the needs from the public health system. In order to support an efficient and effective public health system, all data generated during the course of service provision should be available for research and quality improvement by trusted organisations / researchers who meet minimum requirements for data security and privacy.

Response number	50
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher/ academic/ self employed
Publish response	You may publish this submission

### Fit for purpose

**Overall the content of the Standards are helpful, clear, relevant and workable**

Disagree

**Please outline your reasons:**

I think some of the draft is a bit lazy and does not fully embody the participant stance, appearing a little too practitioner biased biomedically. Technical words colour the meaning more and so it's appropriate to add more language, maybe another level where it portrays more ideology also. Some lacking clear explanation. Research is supposed to be treasured more sacredly.

**The standards are applicable to all types of health and disability research**

Neutral

**Please outline your reasons:**

As above

**The standards balance protecting individuals with the realities of conducting research**

Neutral

**Please outline your reasons:**

As above

**The standards support researchers to navigate ethical challenges in health research**

Disagree

**Please outline your reasons:**

It does not treasure the sacred ness enough **Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Strongly disagree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Neutral

**Standards - reflect the principles of the Treaty of Waitangi:** Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Disagree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Disagree

**Standards - protect and reassure the community:**

Neutral

### **Coverage of ethical guidance**

**The standards adequately cover the ethical challenges that are present in health and disability research**

Disagree

**Please describe the ethical challenges that are missing:**

A bit vague. Little on ethical complexity of designs etc. Doesnt help people to dodge more ethically complex designs if they lack skills, communication skills and language deficits.

### **Merging the observational and interventional guidelines**

**The standards are applicable to both observational and interventional research**

Disagree

**Please outline your reasons:**

I thought the stance was a bit lazy. Experimentalism is not appropriate as a modality. Economically and ethically it is not viable. I think therefore the beginning is not ideal.

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Disagree

**Please outline your reasons or suggested improvements:**

I think the index could have parts to it and chapters. It seems a bit too drafty even for a draft document.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

Sorry I have other deadlines so this is the best feedback I could give with your due date of 28/9/18.



Response number	52
Name	[redacted]
Organisation	[redacted]
Role	Biobank Curator
Interest group	Researcher
Publish response	You may publish this submission

## Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

### Please outline your reasons:

Overall I feel the Standards are well written and a 'formalisation' of what researchers working at a higher level of ethical practice already adhere to.

Importantly they now send a clear message to the research community that ethical conduct is required for the entire duration of a study in every day practice, not just a tick box for an application. This is a fundamental ethical principle that I have championed for many years and include in teaching.

The improved and clarified definitions are very helpful and strengthen the standards, in particular the terminology used for Data identifiability, using the terms Identifiable, re-identifiable and non-identifiable, extremely important in the light of other global regulations such as the European Union General Data Protection regulation which defines the term anonymised data, to mean data with no key code held anywhere in the world.

Overall the Standards are workable but there will always be exceptions for specific situations which will be commented on in section2.

I would hope that HEDC scope of review will be increased to include some applications that are currently considered out of scope. An example would be where research applicants might have applied for departmental review, been requested to submit a full IRB application and then applied for HDEC out of scope. The Standards require that the minimum ethical requirements must be met by researchers whether or not the research requires ethical review by an ethics committee, I am not sure how this could be evaluated if the research is not ethically reviewed ? and I am not convinced this would fall under 'best clinical practice" either.

Overall the authors have produced a good document.

The standards are applicable to all types of health and disability research  
Agree

### Please outline your reasons:

The Standards are designed to ensure researchers think through all the ethical issues. Currently the ethics application forms guide researchers through this process with variability in completeness

between committee application forms. The standards should harmonise all committee's application forms. Hence should be translatable to all types of health and disability research.

### The standards balance protecting individuals with the realities of conducting research

Agree

#### **Please outline your reasons:**

I agree in general with the exception on some elements of the return of research results which, will be addressed in that section.

An overarching difficulty is the variability in ethical reviews from different HDEC and other IRB committee's. The committee's members all come with different perspectives, viewpoints and experience of/with research, which by its nature leads to inconsistency in reviews. Perhaps more training could be provided for ethics committee members with the introduction of the new SOPs derived from these standards?

### The standards support researchers to navigate ethical challenges in health research

Agree

#### **Please outline your reasons:**

The Standards provide a walk through guide.

#### **Overall do the Standards?**

#### **Standards - safeguard the rights and interests of participants in research:**

Agree

#### **Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

#### **Standards - reflect the principles of the Treaty of Waitangi:**

Agree

#### **Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

#### **Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

#### **Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

#### **Standards - protect and reassure the community:**

Agree

### Coverage of ethical guidance

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### Merging the observational and interventional guidelines

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

The Standards are the minimum expected ethical conduct and therefore can be scaled up for higher risk activities. Observational research can be more than minimal risk using blood and tissues from patients, but more importantly is the requirement for the return of research results or incidental findings. With new technologies such as next generation sequencing that can potentially strongly impact on a participants future health, a similar level of standards should be applied.

### Scope of the standards and non-research activities

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

Agree , and I applaud the NEAC working group/authors' recognition of the difficulty in distinguishing the grey areas of research vs clinical activities.

One such is the development of a diagnostic test by a clinical lab scientist vs a scientist in a research lab. Here the question is important; can we find a marker to use to test A (research - ethical review) vs can we validate and standardise this test A to be robust enough to use as a diagnostic test (clinical-diagnostic test development/work up). The Standards scope apply to non-research practices (4.5) however how would these projects be evaluated if ethical review is not undertaken, (IF the development was perceived as non-research ) and I am not convinced they would fall under 'best clinical practice'.

Would additional and practical, ethical practices be included in education and training for qualifications, or Laboratory training in a similar fashion as health and safety is, or as part of a module for an ISO or IANZ type laboratory certification?? - this may very well be met with resistance due to additional business costs!

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. : above.**

### Human tissue

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Overall this is fit for purpose with commentary on specific issues 15.10, 15.13,15.25 below.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Pg 91,15.1 Human Tissue definition 40.

Statement 40 includes 'any derivative from these, including cell lines'. I seek clarification on what the term "cell lines" relates to and request if this could be better defined. I anticipate that this term differentiates between primary cell lines that are derived from tissue collected from a participant with informed consent vs commercialised human cell lines that are currently used as common invitro cellular models, but does it? If the standard did apply to all cell lines of human origin, any new cell line imported into New Zealand would need to conform to the standards and possibly all current cell line use could require each experiment to be logged in a controlled document to fulfill 15.7, 15.9,15.11. which would be considered onerous by researchers.

However any cells from human origin in research should be used in an ethical and respectful manner.

15.13 "must be suitably qualified".

The use of 'must' as a directive in this standard suggests that NEAC might develop or implement a new qualification for researchers involved in tissue collection, use and storage.

"follow current best practice", is this in terms of ethical conduct or in terms of handling and preparing the tissue in a way that it will be suitable for the proposed analytical techniques, may be both? It would be helpful if this statement could be more clearly described because 'best practice' would be appropriate for a biobank with future unspecified use, however a research study tissue " should follow the best tissue handling SOP's that provides the optimum sample quality for the proposed analytical technique i.e. 'fit for purpose'. This conduct fulfills the element of respect for the gift.

15.17.

Suggest adding in the words 'and its associated data' to the phrase 'when the tissue -and its associated data- is used and stored'. This would reinforce the aspect that tissue and it's associated data is of equal value in terms of privacy/confidentiality and needs to be treated accordingly.

15.2 (15.25 Commentary).

Agree that researchers have a duty and responsibility to inform participants on results or incidental findings in principle, however research is experimental by nature and there are situations in health research where the results should be validated by a diagnostic test first. This can be problematic because there may not be a diagnostic test or all of the research sample has been used, there is no remaining tissue to test and it may not be possible to obtain an additional sample (impt consideration for 15.42). In some research situations it may only be ethical to return clinically



significant or clinically actionable individual results. If a study is actively looking for or measuring a known disease factor then a return of research results (and possible funding of diagnostic testing) does need to be planned for. My main concern is for incidental finding results and the proposed requirement for providing counseling which could be very difficult to fund by a research group , especially those who are grant funded.

15.34

I would suggest that researchers working in genetic research should partner with a clinician in the health area being studied.

I am concerned that there appears to be an expectation that researchers would be able to identify incidental results from genetic sequencing data for diseases other than those being studied. When genetic testing for healthcare is performed, the clinicians look at the answer to their question not at all genetic data searching for other possible sequences that might impact on their patient's health. Most researchers generating genetic information would only be familiar with the nuances of the health issue of interest, and would not be able to recognise other disease sequences.

15.35

Participants can be informed if it is known currently, but what happens with new knowledge of disease at a much later time ? This is a huge issue globally and I would like to see a clear direction in the SOPs that limits the liability in New Zealand at least, to when the study was conducted.

## Biobanks

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

### **Please outline your reasons why the section is or is not fit for purpose:**

This Standard section appears fit for purpose and reasonable, however I would prefer a distinction to be made to make this section more relevant between a biobank for future unspecified research, with a custodian (kaitiaki), for multi users and a biobank which arises from a specific study with a subsection of informed consent for future use beyond the life of the study. A multi user biobank by its nature must have strong governance with its membership from multiple disciplines to provide the diverse perspectives required for evaluation of sample use in future unspecified research. By having an independent custodian, this type of biobank is more likely to identify potential research that falls outside what could be reasonably expected by the donor, when they sign their informed consent to donate samples and data to the biobank. At times research that falls into the category of being outside the original intent is not clear and in this circumstance a governance group from a biobank from a study origin, that consists mainly of study investigators, may not have that diversity, expertise or ethical experience to recognise this. I believe this could be addressed in this standard with stronger guidance for governance arrangements differentiating between the two types of biobanks .(continued in specific paragraphs)

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

### **Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

16.10

Biobanks should submit a close down basic plan as part of their ethical approval for biobank establishment. Most biobanks do not have a guaranteed funding source for their lifecycle or that of their data lifecycle. ( Databases require program updates or eventually they cannot be accessed). Therefore a close down plan is essential and should be aligned with the 'ownership ' and hosting institutions capabilities.

16.22

'results of independent audits of compliance'

Maintaining public trust is paramount in biobanking and transparency and an auditable trail from sample and data donation to use in research, is an expectation to fulfill this. 16.22 implies that an independent audit of compliance is required? Who will be carrying this out(MOH)? An important factor will be costs for this. An internal audit is achievable and part of quality assurance. An external audit is always desirable but is it realistic, given I have yet to see an ethics audit for any non-intervention/ observational research. Would a baseline from an international certification program be helpful?

16.26

I would appreciate a clearer description on the statement 'to interfere with their individual privacy in the public interest'. An example would be very helpful. I believe I do know what this means but I'm not 100% sure.

Response number	53
Name	[redacted]
Organisation	[redacted]
Role	Coordinator - Governance
Interest group	Government agency
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

Overall we found the Standards well set-out, clear and readable. We believe combining the interventional and observational standards was a good decision.

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:** Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

The use of data will be an area that will continue to evolve.

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

We believe combining the interventional and observational standards was a good decision.

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

The section on innovative practice is a great addition.

There is now hardly any emphasis on Audit and related activity or quality improvement activity, which has been reduced to two bullet points on page 12. It is recognised that there is much cross-over with observational research, particularly descriptive studies and cross-sectional studies, and having clearer guidance is highly recommended.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Bioethics principles on page 17 should be written in the same order as in the flowchart on page 16, or vice-versa. (Figure 1)

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

Paragraph 6.19 add (link to 6.25) on last sentence

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

7.1 : remove the word 'Islands'

7.10 : remove the word 'Islands'

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

- 9.21 – substantial changes and significantly amend have not been quantified. There is no way of knowing if this refers to the a change of lead researcher, additional blood tests, new outcomes being investigated, etc. Is it wanting researcher to think about, “would this change mean participants may no longer wish to continue?”
- 9.26, some additional letters/words in the last sentence ‘a’ and ‘being’.

- 9.6 'no legal mechanisms for a 'general' waiver of consent, however 9.61 indicates that a waiver 'is legally available for use of health information and human tissue.
- 9.90 seems to repeat 9.69

### Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

#### Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

### Research benefits and harms

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

- 10.14 is a confusing paragraph and does not suitably explain minimum risk.

### Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

- 12.27 Public health studies also come under non-research (investigations and surveillance, page 12). This paragraph needs more emphasis on the differences required under legislation for public health. Also, epidemiological studies also have many features with outcome analysis and this needs to be made stronger.
- 12.40 This new (reinvigorated) emphasis on individual consent in cluster-randomised trials makes using this method near impossible.

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

### **Charging participants**

**Please outline your reasons:**

### **Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Reference to Health Information Privacy Code 1994 is not evident in the standards. The code sets specific rules for agencies in the health sector. It covers health information collected, used, held



and disclosed by health agencies and takes the place of the information privacy principles for the health sector.

- Section 14 – great having this included and detailed. Identifying ownership of data in the same way as tissue makes it more tangible for the common folk. • 14.23 add (link to 9.36 and 9.38 bullet point 6)
- 14.35 Much easier to understand – a welcomed move.
- 14.37 first letter is a number when should be a letter

### Big data and new ways of using data

Agree

**Please provide feedback:**

### Databanks

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Compensation for commercially sponsored intervention studies

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

It would be worth encouraging sponsors to pay ACC levies in NZ to enable studies to be covered by ACC.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Response number	54
Name	[redacted]
Organisation	[redacted]
Role	Research Ethics Administrator
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Strongly Agree

**Please outline your reasons:**

The standards are applicable to all types of health and disability research  
Strongly Agree

**Please outline your reasons:**

The standards balance protecting individuals with the realities of conducting research  
Strongly Agree

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research  
Strongly Agree

**Please outline your reasons:**

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Strongly Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Strongly Agree

**Standards - reflect the principles of the Treaty of Waitangi:** Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Strongly Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**  
Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Disagree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

## Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

The University of Otago Human Ethics Committee (Health) would like to provide some editorial suggestions to clause 8.18. A footnote is include below as it was consider that the Standards need to explain what it consists of..

Clause 8.18

Participants may have diminished capacity to consent due to a number of factors; for example, early dementia or other brain disease, brain trauma, drug intoxication, pain, distress, psychiatric disease or reduced intellectual capacity. Where an individual has diminished capacity, that individual still has the right to make informed choices and give informed consent, to the extent appropriate to their level of capacity. Such a person may be able to exercise the right to consent to participate in research through supported decision-making. Supported decision-making differs from substituted decision-making or proxy consent in that the latter approaches [may] not suitably involve the participant in the decision-making process. The role of supporters (eg, friends, family, whānau) is to facilitate the person's decision-making process[The potential participant should choose these supporters and they should have no conflict of interest [or exert undue influence] .16 The level of support should reflect the level of complexity in a particular study and be sufficient to enable someone to make a decision about whether to participate. 1

Footnote: 1. Supported decision involves assisting a person to make & express a decision which may encompass: explaining information; assisting a person to obtain relevant information; ascertaining the will and preferences of the person and assisting in communicating those preferences; endeavouring to ensure a person's decision is implemented.

## Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

1. Point 12.13 states that “A randomised controlled trial is often the best way of addressing questions about the effectiveness of treatments or preventions.” The University of Otago Human Ethics Committee (Health) (UOHEC (H)) would go further and say it is the best way, or at least it is usually the best way.
2. Point 12.13 defines confounding factors as “variables which influence both the dependent variable and independent variable, causing a spurious association.” Given that (i) confounding factors are variables which are associated with (rather than influencing) the exposure and outcome of interest, (ii) some readers may not understand the terms “dependent” and “independent” variables, and (iii) that confounding can make a true association appear weaker or stronger than it really is (as well as creating a spurious association), UOHEC (H) would like to suggest alternative wording: “variables which are independently associated with both the exposure and the outcome of interest, are not on the causal pathway between the exposure and the outcome, and can distort a true relationship between the exposure and the outcome or create a spurious association.”
3. Point 12.14 lists some ways in which bias can be minimised. UOHEC (H) asks whether it would be useful to base this list on the current Cochrane Risk of Bias Tool, for example: that researchers “give particular attention to the means of randomisation (random sequence generation and allocation concealment), blinding of participants and personnel, blinding of outcome assessment, complete outcome data, and avoidance of selective reporting.” The comment regarding sample size could be put in a separate point as this relates to ensuring the randomised controlled trial has sufficient power to detect a treatment/prevention benefit if one exists (i.e. it is not about bias).

## Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Point 13.12 states that researchers should register their study in the Clinical Trial Registry. The University of Otago Human Ethics Committee (Health) asks if this should read “their intervention study”?

## Charging participants

**Please outline your reasons:**

### Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

The draft ethical standards provide guidance about sending identifiable data overseas for research if the person from whom the data were collected has consented to such transfer (point 14.22).

New Zealand is one of the few countries in the world in which it is possible to link demographic, hospital discharge, cancer registration, maternity, mental health, mortality, pharmaceutical dispensing, and other data across an entire country. Consequently, there appears to be some interest on the part of overseas researchers, pharmaceutical companies, and commercial health data companies in accessing such data. Therefore it would be helpful to have some guidance about the provision of re-identifiable or non-identifiable routinely collected demographic, health, and pharmaceutical dispensing data (e.g. data from the Ministry of Health's national collections) to overseas researchers and commercial companies. While some people might argue that it would be low risk to send non-identifiable data overseas, it can also be argued that there are some important risks to be considered – for example, other countries may have lower levels of data protection than New Zealand; some New Zealand patients may be unhappy about their data (even if non-identifiable) being sent overseas and/or provided to a commercial entity; and overseas researchers are unlikely to be aware of the importance of avoiding a deficit model when discussing health data related to Māori, Pacific peoples, and other groups. If there was a loss of public trust in the sharing of routinely collected data, this could jeopardise public good research in New Zealand.

Big data and new ways of using data

Neutral

**Please provide feedback:**

See above.

### Human tissue

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Recommend that consideration is given to adding a paragraph on the use of cadavers and cadaver tissue for research purposes, from donated bodies. The University of Otago Human Ethics Committee (Health) suggests that contact is made with Emeritus Prof Gareth Jones from the University of Otago Anatomy Department, if an expert opinion is needed.



Response number	55
Name	[redacted]
Organisation	[redacted]
Role	Epidemiologist
Interest group	Academic
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

Combined two sets of guidelines into a single document well which will help to resolve conflicts.

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Neutral

#### Please outline your reasons:

There remain issues around conducting research in some areas that raise ethical concerns because of potential gate keeping.

One of the primary areas this occurs is in relation to research involving pregnant women. The majority of the time there is a requirement or a need to ensure that the mother (and sometimes the newborn) is suitable to be approached to take part in a research study. This tends to occur in general by initially approaching the pregnant woman's lead maternity carer (LMC) to check on suitability.

The issue that arises is that this can and does at times lead to an issue of gatekeeping. This can occur where the LMC does not like or want for reasons of their own choosing to have the woman under their care involved in the research project and will not inform the mother to be of the research project or not allow the researchers to approach the mother to be. This in itself is unethical as it is not allowing the mother to have the chance to be informed and potentially take part in the research, as she never knows about it.

The standards support researchers to navigate ethical challenges in health research  
Neutral

#### Please outline your reasons:

One of the primary and I believe essential areas that is missing in the document is guidelines/rules and direction around locality assessment for both researchers and institutions giving locality approvals. Searching the word locality does not find any instances of it in the document.

Once receiving HDEC approval, locality approvals are required for each research locality at which the research will be undertaken. These locality approvals have become more and more intensive over recent years and would seem at various times to go beyond what their intended purpose is.

The process at many DHB's for example has effectively turned into an additional ethics, and scientific review, even though this is a requirement of the process to obtain ethical approval from HDEC and other ethics committees. Whilst the HDEC process has timelines for processing of applications there are no such guidelines for the locality processes and so research projects can get substantially delayed which has potential implications in terms of funding and thus the ability to successfully complete projects.

There needs to be an oversight of the process that DHB's and other organisations are requiring for locality assessment. This should not require further or repeated efforts for matters that have already been approved. Guidelines around times for locality approvals should also be put in place as they are for ethics committees.

### **Overall do the Standards?**

#### **Standards - safeguard the rights and interests of participants in research:**

Agree

#### **Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

#### **Standards - reflect the principles of the Treaty of Waitangi:**

Agree

#### **Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Neutral

#### **Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Strongly Agree

#### **Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

#### **Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

#### **Please describe the ethical challenges that are missing:**

## **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research  
Strongly Agree

**Please outline your reasons:**

## **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

## **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft**

**standards provide clarity for the regulatory and ethical environment? NEAC notes that they**

**can revisit the ethical advice if the law changes: Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

Response number	58
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Research support and ethics advisor
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

The Standards provide clear guidance and will be applicable not only for health and disability research, but also for other research fields.

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:**  
Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

It is helpful that there is now only one set of standards

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?

Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research with participants who are unable to consent**

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

Yes, the standards explain this clearly.

### **Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

### **Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research conduct**



The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Charging participants

**Please outline your reasons:**

As a University where a large amount of student-led research takes place, the commentary about research as learning activity for students could be expanded and strengthened to provide more guidance to supervisors and ethics committees about ethical issues related specifically to student-led research and how these should be managed.

**Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Standard 14.21 allows ethics committees to provide a waiver for consent if a research study involves accessing data without consent. However, no further information about this process of providing a waiver is provided, criteria for approving a waiver or guidance to ethics committees about the acceptable format of a waiver. It is also not clear what might be acceptable justification for accessing data without consent. **Big data and new ways of using data**

Agree

**Please provide feedback:**

### **Databanks**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Human tissue**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Biobanks**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research with stem cells**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

The Standards require researchers to provide ethics committees with evidence of appropriate professional indemnity. Many institutions like Universities provide professional indemnity insurance as part of the University's risk management and is provide to all researcher staff members. More guidance to ethics committees about what is acceptable evidence of indemnity in these cases would be appreciated.

Response number	59
Name	[redacted]
Organisation	[redacted]
Role	Manager of Research Office
Interest group	Government agency
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

The standards are too long to be a truly helpful, workable guide. While it is crucial that the concepts are well articulated, the authors must consider brevity as an aim in itself.

If "must" appears in a commentary should it not be a standard?

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Strongly Agree

#### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

#### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:** Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Neutral

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Neutral

**Standards - help researchers give due consideration to local and national community views and perspectives:** Neutral

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Strongly Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Strongly Disagree

**Please outline your reasons or suggested improvements:**

The guidelines provide an opportunity for ambiguity around ownership of ethical standards for the close relatives of health research, audit and related activity and innovative practice to be resolved. If this is intended that these activities are in scope then the title for the guidelines should reflect this i.e. National Ethical Standards for Health and Disability Research, Audit and Related Activity, and Innovative Practice. Likewise the Scope section should be clear that all these practices lie within the scope. If it is not intended that non-research activities are in scope then this is not the document where standards for those activities should exist.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

4.6. Non-research activities. Pharmacovigilance (post-marketing surveillance) is a bona fide phase (IV) of the clinical research cycle and shouldn't be listed here.

Also, in the cause of internal consistency, section 18.5 acknowledges Phase IV as clinical research.

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

5.6 should appear as 5.1

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

This section has potential to be a powerful influence on research integrity and enhancing the environment for Maori health research. There is room for improvement nonetheless.

Standards (6.3-6.7). Not all the proposed standards given ought to have the status of standards - some feel more like instructions. The standards should be better defined and reflect an aspirational future-state. For example, 6.7 is a clear standard. 6.4 descends into instruction and the actual standard, that researchers must actively protect Maori collective and individual rights, is buried. There is no standard to reflect that researchers should maximise the degree to which their study can contribute to Maori health outcomes.

The standards include descriptions of good research practice that would apply equally in every setting and do not need to be reiterated solely in relation to research with Maori (e.g. 6.5 Researchers should act with integrity and transparency etc.)

Importance of health research with Maori (6.8 - 6.10). This section focussed solely on addressing inequalities and ignores the importance of research involving Maori contributing to global new knowledge, for instance through genomic or personalised medicine research, and also Maori-centred research not focusing on inequalities.

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

### Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

This chapter is difficult. Please see feedback on specific sections below.

Our Auckland DHB Legal Counsel Bruce Northey says " Has that part of 8.28 and 8.29 – 8.36, which deal with informed consent by children and their privacy, been reviewed by a lawyer? The statements made do not align with how I would express the law, and are confusing."

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

8.18, Remove first sentence (stated elsewhere). In supported decision-making how can the potential participant determine if their chosen support persons would have any conflict of interest?

8.28. Authors must resolve the disagreement of this point with 8.3 (not exclude participants just because they might be vulnerable. They must also resolve the necessity to gain legally effective consent from parent/guardian with the risk outlined in 8.27 that parents and guardians might unduly influence children.

8.28. Is the corollary to the third bullet point that persons under 16 CAN provide their own legally effective consent if they are judged to have the necessary capacity? This should be explicitly stated. If untrue this renders the use of the word "consent" in subsequent points 8.31-8.36 misleading.

8.35. The risk of undue influence by providing incentives for research participation is not limited to children. and does not need to be stated here. A single statement covering all contexts should appear in the research conduct section.

8.37. This section about the participation of women in research is problematic for more than one reason. The statement that women have might be excluded from research is provocative and controversial. In our organisation we review hundreds of applications for research approval every year. In contemporary research women are only excluded from participating if pregnant or breast-feeding and participation could place the fetus or baby at risk. The exclusion of women for any other reason (not withstanding exclusively men's research such as prostate research) has never been proposed in our experience for at least the last 8 years.

8.38. Where this section is repetitive of 8.12 the wording should be deleted. Where the new issue of women having a cultural tradition of decision making in conjunction with a male significant other is raised, the guidelines are unclear about whether this cultural construct has any standing. The draft appears to recommend the standard imperative to ensure individual fully informed, non-coerced consent should be obtained regardless of women's possible preference to leave the decision to her male family members. This is an emerging ethical issue in Aotearoa New Zealand and the guidelines must provide advice researchers feel safe in following.

8.39 and 8.40. As per the feedback about 8.37, this part of the guideline does not reflect the contemporary research setting within which there is no advantage to exclude women of childbearing potential unless there are unknown risks to their unborn or breastfeeding children. Promotion of an imperative to include pregnant or breast-feeding women in research should be balanced by the absolute necessity of doing no harm to babies and unborn children.

## **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

### **Please outline your reasons why the section is or is not fit for purpose:**

This is from Auckland DHB Legal Counsel, Bruce Northey. I would like to register a contrary opinion with the statement in 9.76 that "New Zealand law requires participation in all cases of health research without consent to be in an individual participant's best interests." This statement treats the provisions of the Code, designed, like the HIPC and Bill of Rights, to provide a simple, plain English set of health rights as black letter law. It gives no weight to the grey inherent in any such simple statements, nor to section 3 of the Code, which appears to be as broad a provision as the section 2 rights, and as important as s5 of the Bill of rights: Justified limitations - Subject to section 4, the rights and freedoms contained in this Bill of Rights may be subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

### **Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

### **Please provide feedback with reference to the paragraph(s) in question:**

Colleagues will provide detailed responses in their submissions.

## **Research with participants who are unable to consent**

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

Colleagues will provide detailed responses in their submissions.



## Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

The guidelines must be internally consistent. Participants cannot possibly provide informed consent if aspects of the research relevant to their participation is withheld from them. Must participants not have to provide individual informed consent to meet NZ legal requirements?

9.46 Notwithstanding the above, if researchers of any discipline have a valid need to deliberately misinform research participants they will find no guidance about acceptable of risk of harm in this document. Ethics committees that will use these guidelines to develop their operating procedures will find no guidance about how to weigh the potential for harm against the benefits to society for undertaking the research.

## Research benefits and harms

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

## Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

11.13 - remove. Already covered in section 8.

## Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Pleased to see the acknowledgement that observational research can be high risk.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

12.14 Remove - this information has already been given in 11.9

12.19 Should the intervention also be available after the participant completes the trial if their study doctor believes it to be in their best interest, regardless of whether the results of the study overall have been analysed to prove effectiveness?

## Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Generally fit for purpose other than for a major omission in the section about approaching potential participants. For some research it is acceptable to approach potential participants in person, for instance when they attend hospital clinics, are patients in hospital wards or when they are discharged from wards. For emergency or unplanned intensive care admissions it would be futile to attempt to approach patients in any other way. Observational research seeking the views of the general public might use such opportunistic methods as approaching people at a public venue. The document should provide best practice guidance for researchers when these recruitment methods are rational.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

As per above

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

13.6 "Should" ought to be "must".

13.12 Researchers MUST register their CLINICAL TRIAL RESEARCH in a clinical trials register.

13.22 The document ought to provide guidance about what researchers should consider (and ethics committees) when they propose to identify potential participants from health records and they are not involved in care for the group of patients. Presumably all of the provisos for treating clinicians would apply, but what else?

13.34 "avoid deception and refrain from fabricating online identities" - surely "should not" is clearer.

13.45 Consider removing first line.

13.53 Guidance shouldn't be restricted to intervention studies, high risk observational studies should also have such mechanisms in place.

13.54 Guidance shouldn't be restricted to intervention studies.

13.56 "Should" ought to be "must".

### Charging participants

#### **Please outline your reasons:**

The barrier is high enough .

### Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

#### **Please outline your reasons why the section is or is not fit for purpose:**

The proposed new data identifiability taxonomy is very acceptable.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

#### **Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

#### **Please provide feedback with reference to the paragraph(s) in question:**

14.50 Remove. Already stated in 14.21

### Big data and new ways of using data

Neutral

#### **Please provide feedback:**

Unsure - there may be room within these guidelines for individuals with access to person's personal health information to provide this information in non-identifiable form to commercial

organisations unconcerned with public good and that may derive benefit from the information (e.g. health insurance companies, Pharma).

Can the authors of this document consider how the guidelines can limit such access?

### **Research with stem cells**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

The introduction is clear, relevant and workable.

The standards appear to be based on an exaggerated view of the risks of harm. The circumstance of participants harmed in a study needing to litigate to access compensation are so rare in NZ that the standards are misleading.

18.7 It is not feasible for these points can be accurately conveyed by a member of a research team to potential participants in the setting of an informed consent discussion.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please**

Response number	60
Name	[redacted]
Organisation	[redacted]
Role	Policy and Research
Interest group	Consumer
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

By an large the Standards are helpful etc. We have some doubts about how they could (not necessarily would apply to people with dementia and other cognitive disabilities which we address in the section on consent,

The standards are applicable to all types of health and disability research  
Neutral

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Neutral

#### Please outline your reasons:

See above.

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

Overall do the Standards?

#### Standards - safeguard the rights and interests of participants in research:

Neutral

#### Standards - promote high-quality ethical research for social, cultural and economic wellbeing:

Agree

#### Standards - reflect the principles of the Treaty of Waitangi:

Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Neutral

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Neutral

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

With the caveat about people with dementia and other cognitive disabilities.

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Neutral

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

As noted before and further developed in the section on consent - we have concerns that there is too much possibility for the Standards to be interpreted to deny people with dementia the right to provide their story.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

**Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?

Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

This is clearer than the previous standards and makes clear to researchers what is required.

**Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

We note with approval that the proposed Standards include:

- section 8.3 “Researchers shall not exclude participants from research simply because they belong to a group traditionally considered vulnerable”
- 8.7 “Researchers should assume that each individual has the capacity to make decisions about their participation in a study, unless they have reasonable grounds for believing that the individual does not”
- 8.8 “People who have diminished capacity to make decisions about their in a study are entitled to make informed decisions to the extent of the level of their capacity” and
- 8.13 “ researchers must exclude making judgements about excluding such groups based on stereotypes.” It is important that people with cognitive disabilities are able to participate in research.

As written the standards do not prevent individual with dementia or other cognitive conditions from taking part in research. However researchers with people with dementia and other cognitive concerns report sometimes report having difficulty obtaining ethics approval (both in NZ and internationally). For instance we were in a meeting where one of the members wanted to decline a proposal on the grounds of what he/she thought that someone they knew would have thought before they developed dementia - without any personal experience that might or might not have happened. We assume this leads some researchers to not considered research with people with dementia and other cognitive concerns.

We think that this could be addressed by a short addition to Section 8 (as is already done with some other groups) which addresses the need for and possibility of ethical research with people with cognitive difficulties. This would make it clear that research with people with cognitive difficulties is both possible and desirable with the appropriate protections.

Following is a list of the criteria that we believe are necessary for useful and safe research with people with dementia and other cognitive difficulties. While we accept that the Standards themselves are not a place for this list some reference to a place to find a list of issues to be addressed (which the researchers should address) we include a list of what we would expect them to address. This list would show the need to consider and highlight:

- Informed consent or supported informed consent will be obtained
- The researchers will show evidence that previous similar research has been in the best interests and preferences of people with cognitive difficulties
- any test to ensure that people can make an informed decision should be brief and not intrusive or upsetting for the person with dementia. An example our researchers have found it useful (and non-intrusive) is the Older Adult’s Capacity to Consent to Research (OACCR) scale
- use the safe and inclusive research approach promoted by groups such as The Dementia Engagement and Empowerment Project (DEEP)
- people being interviewed should previously have been informed of their diagnosis (before being approached by the researcher) if they are being interviewed because they have dementia.
- where and if the research requires people who have not been formally diagnosed the person should be cognizant of and accept the possibility that they have a cognitive condition
- that care partners and or health professionals are aware that the person with dementia is to be approached for willingness to take part in the research
- ensure that the interviewers have been training about dementia (or other cognitive difficulties)



- minimise the complexity of any supplementary follow on requests for consent eg for using the data for other research

Sorry but I can't find the sections on participants unable to consent or deception (my fault I am sure) so I'll add the sections here.

Unable to consent:

Social research ie where people with dementia are active participants in the research must always include informed or supported consent. We believe there are different ways to obtain this – but there are advantages to a simple consent process such as the Older Adult's Capacity to Consent to Research (OACCR) scale.

Researchers should have an awareness of the possibility that a person may withdraw that consent during the interview or to do the interview over two sessions.

Informed consent is critical for clinical research.

Deception

There are unlikely to be circumstances in which deception is appropriate for clinical or social research for people with dementia or other people with dementia or other cognitive disabilities.

Response number	61
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Government agency
Publish response	You may publish this submission

## Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Neutral

### Please outline your reasons:

The document layout is generally clear, but could be made more user friendly by ensuring that more cross-referencing is done between sections that strongly relate. There are numerous instances of this e.g. linked recruitment to informed consent. This will be important to ensure that information isn't missed or overlooked by researchers because it is only located in a section that may not be obviously relevant.

The standards are applicable to all types of health and disability research  
Neutral

### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Agree

### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Neutral

### Please outline your reasons:

See above re clarity.

### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:**  
Neutral

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Neutral

**Standards - reflect the principles of the Treaty of Waitangi:**  
Neutral

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Neutral

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Neutral

**Standards - help researchers give due consideration to local and national community views and perspectives:** Neutral

**Standards - protect and reassure the community:**

Neutral

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Neutral

**Please describe the ethical challenges that are missing:**

See section answers.

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

See answers to first question.

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Neutral

**Please outline your reasons or suggested improvements:**

See section answers.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

We think the Māori aspects of the Standards are fit for purpose and very helpful for those engaging in Māori related research.

Cultural rigour is an important concept but it is unclear exactly what it entails. Perhaps make it clearer that you are encouraging researchers to work with the understanding that designing a culturally sound study should have the same importance as scientific rigour (that they are equal partners in research design).

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

As to whether the Standards covers all relevant ethical issues, a key objective of the standards is to “reflect the principles of the Treaty of Waitangi” (p.3). The principles are then later defined in section 2.3 as “partnership, participation and protection” (p.5). While these three principles are certainly well known and used widely, additional Treaty principles that are also relevant to ethical considerations have been identified in New Zealand case law and by the Waitangi Tribunal. These include the principle of rangatiratanga, the principle of equality (rite tahi) and the principle of redress (whakaoranga). Many of these additional principles link well to the statements in section 6.2 (p.20).

We would also suggest the inclusion of the Māori terms for partnership, participation and protection, namely ‘mahi tahi’, ‘whai wāhi’ and ‘kaitiakitanga’. The document is also missing macrons on the word ‘Māori’ in multiple places throughout.

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Neutral

**Please provide feedback with reference to the paragraph(s) in question. :**

It's good to see that consultation is at the forefront of this section, but there could be more guidance about what consultation looks like. Many researchers struggle with this, especially those not from New Zealand or those who do not have easy access to an institutional ethics committee.

It would also be helpful to include some more specific guidance to researchers to ensure Māori are not overburdened with desires for collaboration (which often isn't true collaboration).

## Research involving Pacific peoples

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

Many of the comments pertaining to Research involving Māori are also relevant here. Generally it would be easier for researchers if this section had the same layout and headings as Research involving Māori. Currently it is confusing that the two sections look quite different. Some of the same information is present, but is structured differently; some information is missing in this section and it's unclear if researchers should refer to the Māori section in conjunction with this section.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

See above.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

See above.

### Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

This section contains elements of paternalistic language in references to “vulnerable” groups. E.g. ‘Research in women’, ‘Research in children’. Should this not be ‘Research with’ or ‘Research involving’?

It may not be necessary to provide a list of ‘traditionally vulnerable groups’ in 8.12. Currently, the language used to describe those groups is somewhat old fashioned, and unfortunately the inclusion of groups in a list like this continues to reinforce the attitude that all members of these groups lack some kind of capacity to understand the research and give consent. Instead, it may be better to include a nuanced definition of ‘vulnerable’ that researchers can apply to groups of participants. The previous NEAC guidelines for intervention studies are superior in this regard.

Large sections of the ‘Research in children and young people’ section are almost identical to the Australian National Statement. It is highly desirable in a set of Ethical Standards to apply established rules of referencing sources.

We have attempted to apply the ‘Research in children and young people’ section to an existing application to our institutional ethics committee. We found that the section was difficult to apply and contained conflicting guidance. The study contained a particular ethical issue - whether young people may participate in a study without seeking prior consent from their parent/guardian. The current drafting of the section contains the statement, “if the child is under 16 years old and lacks the necessary capacity to give legally effective consent, the researcher gets consent for the child to

participate from their parent or legal guardian” (8.28). This, and other sections, imply that young people can give consent before they reach the age of 16. But later in 8.28 it states that “if a child turns 16 during the course of a study, the researcher seeks their consent to continue participation”, implying that no young person under the age of 16 can give proper consent to participate. In 8.34 it is implied that a young person under the age of 16 cannot withdraw their data or tissue from a study.

We think it is important that the advice in this section is not ambiguous. We would suggest that an approach be adopted that allows researchers to take into consideration the many factors that might be impinging on whether or not a young person should or can be able to consent for themselves rather than have it be limited to a consideration of chronological age.

We suggest you refer to the Innocenti (Unicef) ERIC (Ethical research involving children) resources.

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

More detail is needed in the section on electronic consent.

This section indicates that the information provided to researchers to elicit informed consent should not be excessive (9.31). This statement is somewhat contradicted by the very long list of information in 9.34.

Researchers often request guidance on the storage of consent forms. Information on consent form storage would be welcome in this section.

The section outlining unspecified consent for future use (9.36) is too broad and is in tension with the need to provide informed consent. We suggest that guidance is included to the effect that researchers must provide information to participants on the likely types of use, and allow the participants to include restrictions to ensure their data or tissue is not used in an unexpected way.

The section on deliberate deception (9.45) needs strengthening. Researchers need greater clarity on when they may deliberately misinform participants. What are the very limited set of conditions where this is ethical?

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

## **Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

### **Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

In the same manner as sections 6 and 7, more guidance could be included about the merits of participants having a say in research design and the potential benefits.

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Researchers can sometimes struggle with the provision of koha and drawing the line between koha and inducement. More guidance here would be welcome.

The section relating to advertising studies and the information required in adverts (13.26) should include the provision of the relevant Human Ethics Committee approval number.

## Charging participants

**Please outline your reasons:**

### Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

The updated definitions of data identifiability, ostensibly from the Australian National Statement, are an improvement. However, the National Statement has recently been updated to reflect a more nuanced approach to data identifiability (3.1). We suggest that the working group review this document to ensure alignment with practice in Australia.

Under the current drafting, it is not clear how re-identifiable data should (and will) be treated in the process of ethics review. As re-identifiable data is only one step – sometimes a very small step – away from being identifiable – will/should committees treat re-identifiable data in the same way as identifiable data for the purposes of ethics review? If it should be treated differently, how should/will it be treated? Again, reviewing the revised National Statement which treats the identifiability of data as a continuum could assist in this regard.

In addition, we have some more detailed feedback on this section:

- 14.17 states that data should be stored and used in the least identifiable form possible – more guidance on what this means in practice and how this can be achieved would be welcome.
- 14.24 – is consent required for linking reidentifiable data? Linking such reidentifiable data sets may make the data identifiable.
- 14.27 states that data linking should only be done by an appropriately trained person – what does this mean in practice? What is appropriate training?
- 14.28 is somewhat vague – how long should data be held for?
- 14.29 states that researchers should remove all identifiers – does this include direct and indirect identifiers? What should researchers do if some of this identifying information is necessary for the study in question?
- 14.48 – should refer back to the definition of sensitive information provided earlier in the document.

### Big data and new ways of using data

Not Answered



**Please provide feedback:**

Response number	62
Name	[redacted]
Organisation	[redacted]
Role	Research Fellow
Interest group	Academic
Publish response	You may publish this submission

## Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable

Neutral

### Please outline your reasons:

Overall, the document represents a comprehensive framework for ethical assessment of research in health and disability research; it sets the context and scope for the application of the standards relatively effectively, however there is a good deal of variation in the quality of coverage of particular issues, some duplication and some gaps. These are addressed in detail in the remainder of our submission. In relation to the specific dimensions of fitness for purpose set out above we would highlight the following:

**Helpful:** The attempt to delineate and codify the broad array of concerns related to the conduct of health and disability research is relatively well captured in the document. The attempt to include commentary about values and context, and to make the guidelines not just instrumental and formulaic is a commendable approach and likely to be helpful for researchers in establishing a deeper understanding of principles and standards which apply to the practice of ethical research. Nonetheless, in some areas the commentary may leave researchers unclear about what is required to meet the standards as the range of factors to be taken into consideration is large and the contextual features are complex.

**Clear:** The discussion around values and context at the same time results in places in a lack of clarity or consistency. The document is generally challenging to read given its length and density and so readability and accessibility are a challenge to overall clarity and flow. It is possible that either a supplementary document or training may be required to assist researchers to apply the standards well.

The document uses the language of “research” and “non-research”, however it may be clearer to recognise that these may be research (understood as the advancing of knowledge and understanding) to which the National Standards applies, research to which the Standards do not apply and, in the case of medical innovation research and similar, research that should aim to meet the Standards.

**Relevant:** The Standards aim to apply to all research relevant to health and disability, however they appear to take as the paradigm for research: 1) clinical research that involves risk of physical or psychological harm, 2) an intervention involving a person’s body or data, and 3) the testing of a particular hypothesis or intervention. This is likely to be inadequate for providing ethical guidance

for health related research that considers social factors affecting research or observational studies of behaviour relevant to health (eg illicit drug use), and links between social and health inequities. The treatment of special cases of research activity in section 12 compounds the privileging of clinical interventional research.

The inclusion of Māori principles embedded throughout the document is commendable. However, the extent to which they are integrated in various chapters differs. The chapter on "Research involving Māori" is important contextually and relevant to the whole document; yet, for example, the final three chapters scantily address or apply these principles.

The document conflates health and disability. We understand that the language of "Health and Disability Services" is an artefact of NZ government structures, however health and disability are two distinct areas of research, paradigmatically different, even though their subject matter may sometimes overlap. In the draft National Ethics Standards there appears to be an assumption of the primacy of the clinical or medical in the Standards, marginalising the social context that more commonly is the focus of research which aims to capture the lived experience of disability. By way of example the section on Strategic Focus (2.8) makes mention only of health inequalities and inequities and does not acknowledge social inequalities and inequities experienced by people with disability. The term 'patient' is used inappropriately in some instances (eg. 4.6) in the document to refer to research participants – this usage is not relevant to research addressing the social context of disability, where the issue under consideration is, for example, the way that public transport design contributes to the social disadvantage (inequitable life opportunities) of people with disability who cannot engage in paid work if they lack reliable, cheap and accessible transport.

Workable: The document is very long and somewhat challenging to navigate and there is potential that this will be a disincentive to researchers in reading the whole document and using it to shape the conduct of their research. Our suggestion would be to rethink the overall structuring to aid accessibility, navigation and readability by separating background discussion of issues in depth from the practical guidelines for researchers who are seeking a more step by step instructional approach to the content. This could be achieved via the use of hyperlinks between sections to which there would be no impediment as the document is designated as online only. As commented above, there is need to consider the education process for researchers who are expected to use the Standards.

**The standards are applicable to all types of health and disability research**

Disagree

**Please outline your reasons:**

Some sections of the document (e.g. section 12 on types of studies) indicate a degree of breadth of application. The scope section also (notwithstanding comments under Q7 and Q8) positions the document as applicable to a broad variety of different activities.

However, qualitative and ethnographic research seem poorly reflected throughout. This is especially the case in relation to consent and even in the 'types of studies' section. At many points the standards seem to assume a paradigm of medical research construed more narrowly, such as the testing of interventions to diagnose or treat disease. Of particular concern in this respect is the treatment of research that may justify the waiving of the requirement for consent (eg observational, epidemiological, some secondary research).

Most prominent among our concerns is the limited applicability of the document to disability research. The document takes as its starting point health research and very little effort is made to

distinguish this from disability research or to present a positive account of the nature, norms or aims of the wide variety of studies that fall under the umbrella of 'disability research'. Generally, throughout the document health and disability are conflated. From a disability lens this often means that the guidance is either contradictory to best practice in disability research or disability is obliterated and equated with ill health.

There is an emphasis on similarities between disability and health, and on the connections between dependence and disability. There is an assumption that dependence is invariably harmful and that independence is the proper goal of health and disability research. Dependence is an inevitable feature of human life and the appropriate goals of disability research can be many and varied. The sentence on disability research in the table (4.3, 3rd dot point) is inadequate. Knowledge from this research may not be just about support but to understand and explore the experience of disability in context. Furthermore, the reference to types of support is both narrow (focused on inclusion, independence and participation) but also vague. Included in what? Participate more in what? Independent in what way? Specifically on independence, we note that the statements about supporting people with disability to be more "independent" require clarification. For example, the importance of interdependence for independence should be articulated in the document (e.g. 1.2).

### The standards balance protecting individuals with the realities of conducting research

Neutral

#### **Please outline your reasons:**

Throughout the document there is an obvious tension between protecting individuals and the conduct of research, and it would probably be more accurate to say that the standards make a serious attempt to balance the protection of individuals with the realities of research, but don't always succeed. There are things that could be done to shift that towards 'agree'.

The aspiration is clearly to achieve this balance. This means that some statements are necessarily aspirational and these need to be flagged up as such, or else toned down to make them more realistic. An example is 4.9: Health care must always be tailored to the individual needs, circumstances and medical condition(s) of each consumer. In practice this is an impossible demand, given limited resources, time and knowledge. Impossible demands encourage researchers not to take them, or other more achievable goals, seriously, and that can tarnish the whole enterprise of research governance. In other instances there are aspirations that require social, political or other change to be achievable, i.e. are dependent on external factors beyond the control of the researcher. For example, the requirement that research with and for Maori or Pacific Islanders be conducted with 'cultural rigour' is absolutely right and to be endorsed, but problematic if it is in a context where researchers can not gain access to this kind of expertise, e.g. because of lack of training or other resources.

The document could reflect the aspiration of protecting individuals by recognising that some individuals and groups wish to conduct research that explores and explains their own circumstances and that such research led by the relevant communities may well pose fewer risks of harms to individuals, but may not be practicable for all research questions.

It's very helpful that the chapters on Maori and Pacific Islander populations give specific references to guidance on good practice, and it would help to have pointers like these in other chapters where relevant. Again, this is about making the aspiration easier to achieve.

One place where the balance between protecting participants and fostering research really falls down is in the discussion of informed consent in chapter 9. Subsection 9.31 says firmly that: Informed consent involves balancing participants' right to be fully informed against not overburdening participants with information that reduces their ability to provide effective informed consent. Participant information sheets should not contain excessive information. Their main purpose should be to inform participants, rather than to protect researchers or sponsors or to achieve any other purpose. Nevertheless the following outline of areas to be covered is extraordinarily long and would be very demanding for both participant and researcher. It could present a significant barrier to carrying out research, and it might be argued that it is a barrier to the proper protection of participants (rather than of the researchers). We wonder whether the guidance could be divided up into a set of core information relevant to all research, with additional subheadings for particular types of research e.g. For studies involving tissue use the following additional information should be included: [...]

This final point about length also applies to the the draft guidelines overall. A lot of the background discussion is valuable and it should be available somewhere, but for everyday research, a much shorter summary of the guidance, with links to further discussion where appropriate would be preferable, so that researchers can easily identify what they should be doing.

### The standards support researchers to navigate ethical challenges in health research

Neutral

#### **Please outline your reasons:**

The Standards provide a great deal of useful guidance to researchers in navigating a large number of complex issues relevant to health and disability research. There are some respects in which we think they could better support researchers, with clearer advice on approaching and resolving ethical challenges in their research.

Before providing our comments on the Standards, we wish to record that we do not view ourselves as appropriately placed (as Australian (and UK) academics) to comment on the adequacy of the Maori principles in the document and the alignment of the document with the Treaty of Waitangi. We do, nonetheless, support the approach taken to articulating the values informing specifically Maori concerns and the use of Maori principles alongside the values underpinning Beauchamp and Childress' principles.

#### General comments

1. The Standards give prominence to 'independence' as an aim of health research. Independence is first mentioned in 1.2 and appears throughout the Standards. Holding this up as a value has been strongly criticised for tending to elide and devalue aspects of relationships that may involve dependence, interdependence and relational autonomy; and for suppressing the ways that autonomy, including senses of independence, can be supported by these aspects of relationships. While perhaps this is introduced because it is seen to balance the focus on group solidarity arising in other parts of the Standards, the way it is discussed throughout the Standards assumes a conception of independence that will be in conflict with solidarity and interdependence, rather than compatible with them.

This issue also arises in 5.8 where autonomy is described in a way that reduces it to a matter of consent and preference. This conception of autonomy is problematic, failing to recognise the complex and contextual ways that autonomy can be undermined or supported (see e.g. Mackenzie 2010). There are dangers here in giving researchers the impression that providing information and gaining consent is all that is needed for achieving respect for participants; and more generally, for providing them with a false standard by which to think about the ethical status of their research in promoting an overly simplistic conception of ‘independence’ as a goal. We suggest reworking the explanation of autonomy to recognise these issues (in their more recent editions, Beauchamp and Childress now recognise relational autonomy as the more appropriate conception). While there are indications that some of the assumptions about dependence and independence may be embedded in other regulatory documents it would be worth examining assumptions surrounding these concepts and refocusing the framing of these values along relational lines as far as possible.

2. The discussion of vulnerability in its present form is inadequate and likely to confuse. The standards clearly aim to emphasise that vulnerable people should not be excluded from research, but also include various statements about avoiding undertaking research on vulnerable people where less vulnerable people could serve the purpose of the research. These statements are in tension and could be interpreted in a number of ways, some of which could become paternalistic and inconsistent with the aim of non-exclusion. We take this difficulty to relate to the way the Standards approach vulnerability, which reduces vulnerability to membership in ‘special groups’ who need ‘specifically considered protection’ (which is not elaborated upon). An alternative is to recognise that vulnerability is both universal and specific, and to encourage researchers to take into account what people are vulnerable to, and whether/how research might create, exacerbate, or otherwise interact with the actual vulnerabilities that participants may experience (Rogers and Lange 2013; Lange, Rogers and Dodds 2013).
3. As we have discussed in our responses to other questions in this Consultation, the language and framing throughout the Standards tends to assume a clinical model of research. This could either influence research decisions, or mean that those engaged in other kinds of research find the guidance less useful or clear. Similarly, there is a lack of discussion or reference to the responsibilities of universities, hospitals or research organisations, as a result the researcher is presented as not being embedded in an institutional context.
4. We applaud the focus on engagement and consultation with communities generally, and specifically with Maori and Pacific people and communities in Chapters 6 and 7. The inclusion and encouragement of co-design of research is especially laudable (co-design of research between researchers and participants could be further emphasised). We also appreciate that various aspects of the Standards are left vague in these chapters, perhaps intentionally, given that they necessarily refer to intangible but important aspects of relationships and procedures. Nonetheless, we are concerned that this vagueness may make the Standards less likely to guide practice or to end up encouraging rote consultation/engagement procedures. It is certainly difficult to guard against this in setting standards, but some suggestions to combat this are:
  - For terms like ‘engagement’, ‘meaningful engagement’, ‘meaningful relationships’ (7.5), or ‘reciprocal processes’ (7.14,) definitions might be offered (and it maybe useful to include at least some of these terms in the Glossary). Where definitions are not appropriate, clearer advice might be given by providing examples or simply by clarifying why there is difficulty in such definitions

and stating that researchers need to think through how these things can best be achieved in their research context.

- It might be emphasised more and earlier that engaging and consulting with research populations early can improve the quality of the data in a number of ways (e.g. better recruitment, more meaningful research question, clearer outcomes). Tying these matters more clearly to the scientific integrity of a study may be motivating for researchers.
- A statement of where researchers might turn for further advice on consultation might be included in the document.

Specific comments:

1.6: The statement in 1.6 is not very clear and could confuse in cases where there are inconsistencies. This is more clearly stated in 3.7, so perhaps this wording could be used in 1.6.

2.8. The distinction between health inequalities and inequities is not very clearly stated. Definitions of both concepts refer to determinants of health and, at various points in the document, both are indicated to be unfair (contra the way the distinction is more often made). The intended distinction here seems rather to be to do with measurability, but it is not clear why that should be of moral relevance, or what its moral relevance is taken to be in this document. Overall the distinction does not seem to be doing any clear work in the Standards. At present its inclusion seems more likely to add to confusion than to clarify.

3.21: The should/must distinction, as described, is not very clear and doesn't seem very useful as a definition/guidance. How is 'should' different? Are clearly detailed and justified exceptions possible for both 'must' and 'should', or only 'should'? If both, then in what sense is 'should' less strong?

## References

Mackenzie C. 2010. Conceptions of autonomy and conceptions of the body in bioethics. In *Feminist Bioethics: At the Centre*, ed. JL Scully, L Baldwin-Redgrave, P Fitzpatrick. John Hopkins University Press.

Rogers W, Lange MM. 2013. Rethinking the vulnerability of minority populations in research. *American Journal of Public Health* 103(12):2141-2146.

Lange MM, Rogers W, Dodds S. 2013. Vulnerability in Research Ethics: A way forward. *Bioethics* 27(6):333-40.

## Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:**

Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Neutral

**Standards - reflect the principles of the Treaty of Waitangi:**

Neutral

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Neutral

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Disagree

**Standards - help researchers give due consideration to local and national community views and perspectives:** Neutral

**Standards - protect and reassure the community:**

Neutral

### **Coverage of ethical guidance**

**The standards adequately cover the ethical challenges that are present in health and disability research**

Neutral

**Please describe the ethical challenges that are missing:**

Starting in Ch 5, the document begins covering both Te Ara Tika and the western bioethical principles that will (or should) govern all types of research, both observational and interventional. The document does a good job of reviewing these primary ethical principles as they pertain to health research, and there are additional substantial and important sections devoted to capacity to consent and informed consent, but there is little mention of how these principles might change or be differently focused in research specifically involving individuals with various types of disability or experiencing chronic conditions. The document as it stands seems to (as we have pointed out elsewhere) conflate health and disability. It does not take into account various models of disability, and it leaves out descriptions and discussions of relational autonomy and the often positive nature of interdependence (these issues have also been articulated in the response to Question 2).

### **Merging the observational and interventional guidelines**

**The standards are applicable to both observational and interventional research**

Disagree

**Please outline your reasons:**

As mentioned earlier, the Standards assume that research is paradigmatically interventional and clinical. It is not clear how, for example, a researcher would use these Standards in the design and conduct of a research project involving observation of the behaviour, for example of groups of school children presented with new playground equipment and how they interact with the equipment and each other (for example to assess whether the design of a school yard may influence levels of physical activity in school children), or how a public health researcher would use them in conducting observational research on illicit drug use.

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Disagree

**Please outline your reasons or suggested improvements:**



In its current form we feel that the scope section will be difficult to use for two reasons. First, because the status of the two ‘grey areas’ (non-research practices and innovative practice) under the Standards is not clear, despite the detailed treatment that these topics receive. Second, due to limitations of the definition of health and disability research, and an apparent assumption throughout the Standards that the paradigm case for research is clinical research (which is narrowly understood).

On the first of these issues, it would be helpful if there was an indication under the top heading of the section on the precise status of “relevant non-research practices” and “innovative practices that are not subject to these standards”. In the current draft it remains unclear whether these are strictly speaking outside the scope of the Standards, but may nevertheless be usefully informed by the document, or whether these practices do fall under the scope of the Standards despite not being research. The section on innovative practice also seems somewhat disorganised, with many suggestions for good practice currently appearing under the “innovative practice” heading rather than the “good practice in innovation” subheading.

On the second of these issues, we note that the definition offered in the scope section is quite broad and does not provide much support to the user in making decisions about applicability. In view of this, the assumptions about health and disability research implicit in other sections will play a role in how the Standards are interpreted and applied. We are therefore concerned that throughout the Standards it appears to be assumed that the paradigm case for research is clinical research that involves 1) risk of physical or psychological harm, 2) an intervention with a particular person’s body or data and 3) involves testing a particular hypothesis about a disease mechanism or therapy. This is likely to be inadequate for providing guidance for health research that considers, for example, social factors affecting health; research on issues related to the wellbeing of people with disability that result from factors such as access to welfare, housing, meaningful work, social inclusion. We would argue that research on health and disability ought to be inclusively understood and that the ethical standards should be framed to account for research on issues related to disability which may not involve physical interventions with individuals.

We note that this issue is of particular concern in relation to disability research. At present health and disability are elided, with disability understood as (or primarily as) a health concern. It seems that the language of “health and disability” is treated as a package, not as two related but distinct areas of potential research.

Three general suggestions for addressing these issues are:

1. It would be useful to clearly distinguish disability research and health research.
2. Section 12 on types of studies allows for plurality of purposes and methods of research. It might be beneficial for the scope section to clearly cross-reference section 12 as offering more detailed insight into the breadth of research encompassed by the statement.
3. Ensure that the scope section emphasises the idea of research as focussed on discovering knowledge, expanding understanding, testing alternative treatment relevant to health and disability and so on. One potential way to achieve this is exemplified in the 2018 update of the Australian National Statement on Ethical Conduct in Human Research. The Australian National Statement’s section on “Purpose, Scope and Limits of this Document” places research participants at the heart of the definition. Asking “What is human research?” By answering this

question in terms of forms of participation by people in research, the Australian National Statement picks out something important that cuts across different research questions and methodologies as well as use of human tissue and data (Australian National Statement on Ethical Conduct in Human Research 2007).

## References

The Australian National Statement on Ethical Conduct in Human Research, 2007 (updated 2018) pp 6-8.

([https://www.nhmrc.gov.au/\\_files\\_nhmrc/file/publications/national-statement-2018.pdf](https://www.nhmrc.gov.au/_files_nhmrc/file/publications/national-statement-2018.pdf)).

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

4.1. This section seems to need a clear introduction indicating how it is organised and foreshadowing the three subsections (Defining the boundaries; Applying the standards to non-research; and Innovative practice).

4.3, dot point 3: "support people with disabilities to be included, participate more and be more independent" - This statement is vague. Included in what?

Participate more in what? Independent in what way?

4.5. "However, from an ethical point of view, the principles and the standards apply to all practices where they are relevant." This seems overly vague and not particularly useful, especially in a section delineating scope.

4.6, box dot point 6: " It should provide feedback primarily to the service, although it may also involve a more general publication or presentation of its findings. Access to confidential medical and personal information the service holds should be restricted to those individuals the service provider employs or contracts, the funder of the service, or an agency responsible for overseeing the safety and quality of the service. Such information should be used solely for the purpose of auditing a service." - this prescriptive material seems out of place here.

4.7-4.15. "Innovative practice" - This section could include something about innovative practice sharing some similarities to research (e.g. in terms of risk to patients/participants, challenges for informed consent) even when it is not properly regarded as research.

4.9. "Health care must always be tailored to the individual needs, circumstances and medical condition(s) of each consumer." Perhaps better phrased as "...as far as possible...". Otherwise a very high aspiration!

4.10. "It is therefore important that all health interventions follow the principles of best clinical practice." Another prescriptive comment; is this the right place for it?

4.13. "Innovative practice must only be undertaken by health practitioners with appropriate qualifications and expertise and for the purpose of treating a specific medical

condition of an individual consumer or consumer group.” Again, is this scope of guidelines chapter the right place for these prescriptive statements?

4.14. “Appropriate safeguards should be in place to ensure that independent clinical assessment occurs through the treatment process so that, should it become apparent the innovative practice is not achieving positive results or is exposing consumers to unnecessary harm, consumers can be shifted to standard treatment protocols.” See above.

4.18. “A challenge is identifying when difference from existing practice requires research, when the time has come formally to research an innovative practice, and what the nature of the research should be.” Which differences & identifying the right time. The IDEAL group in the UK have done a lot of work on when an innovation (in surgery) is ready to be subject to research. Some of the principles they identify may be applicable here (Hirst 2018).

4.21, 2nd sentence: “For example, fully informed consent to the use of innovative surgical techniques or devices is required.” Presumably informed consent is expected in usual practice too. Is it worth clarifying what would be different about this requirement (if anything more than just informing them about the innovativeness and so on).

4.22. last sentence: “A similar level of openness may be difficult to achieve in a more commercial setting, such as medical device manufacture; and the commercial imperative (e.g., commercial sensitivity) may triumph over the ethical imperative.” This final sentence sounds a bit like it's saying that this is difficult so it's okay that the commercial sometimes triumph over the ethical imperatives - may be worth saying a bit more here to give some guidance?

## References

Hirst, Allison, et al. "No surgical innovation without evaluation: evolution and further development of the IDEAL Framework and Recommendations." *Annals of surgery* (2018).

## Ethical principles

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

### **Please outline your reasons why the section is or is not fit for purpose:**

We recognise the value and importance of aligning Te Ara Tika principles and Bioethics principles in this document; however the bioethics principles are presented as unproblematic, despite nearly forty years of debate within bioethics about the workability of this approach to ethical pluralism. We have noted above the recent revisions to the principles in Beauchamp and Childress to recognise relational autonomy, there are also limitations to principlism if it is presented without guidance on how to weigh competing principles (e.g. in research, respect for participants and their autonomy is often viewed as outweighing potential beneficial outcomes for communities, but the standards do not provide guidance on how to prioritise principles in the case of conflict.)

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

### **Please outline any missing ethical issues or principles:**

Given that the document mentions increased independence as a goal several times, it would be helpful to describe which areas of independence individuals with disability might strive to increase (though this will vary across groups differing in age, gender, disability, etc.) Some examples might be helpful. Additionally, a definition of interdependence (and the importance and validity of it for everyone) might be helpful; this could be relevant in the revised section on vulnerability.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

5.2. Remove the hanging bracket at the end of the first sentence.

5.3. While Beauchamp and Childress' principles are widely used they are not undisputed and not the only possible approach to research ethics (as indeed the use of Maori principles in these Standards demonstrates). We thus suggest rephrasing this point rather than introducing these as 'the bioethics principles'; perhaps something like, 'Several other bioethical principles are widely recognised and have been used...'?

5.11 Whilst the section anticipates that there may be a conflict between principles, further guidance could be given about how to make judgements in these circumstances. This might be a good location for further advice about what researchers might do where they encounter difficulties (e.g., links to advice documents or agencies).

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Not Answered

**Please provide feedback with reference to the paragraph(s) in question. :**

It may be useful to define a term for people who are involved in engagement or consultation, and to keep this clearly distinct from the way that 'participant' is used to refer to people in research studies. We would suggest including 'engagement' in the glossary.

6.3. The explanation of 'cultural rigour' might be included here instead of in 6.4, and might be usefully expanded.

6.11-6.16 We welcome the inclusion of guidelines on engaging and consulting early. These statements about the value of engagement might also include its contributions to the scientific integrity of a study, for example it can improve the quality of the data through better recruitment, more meaningful research questions, and other benefits.

6.18. It could be clarified how consultation plays a role in ensuring that research contributes to “health status of Maori”. This may also need rephrasing as it seems to refer to ‘improving’ this health status (?).

6.20. It may be worth clarifying (here or in chapter 13) what is expected surrounding reimbursements for people’s time in consulting with researchers.

Box 1. Typo: ‘collectivises’

6.27. The final point here about the reason to collect ethnicity data seems to us a very important one for researchers to appreciate. Emphasising this point and placing it sooner might be worthwhile, and it might be incorporated into our suggestion above (relating to 6.16).

## Research involving Pacific peoples

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

7.3. The previous chapter included the table with the different degrees of Māori involvement from research not involving Māori to Kaupapa Māori research which we found helpful. Would a similar table be relevant here?

7.5. As noted above, we realise some of the statements in this chapter such as “meaningful relationships” may be intentionally vague, but would raise concerns about their being left entirely open to interpretation. Can some additional clarification be included on what would count as a meaningful relationship, potentially an example?

7.7. Is it possible to move the explanation of “Pacific dimensions of health” or a briefer statement of what this means, up to here?

7.10. Some of the ideas here could be more clearly explained or more clearly phrased, for instance what ‘providing’ a view of health is and when it is appropriate; and what a ‘genuine’ relationship will look like.

7.12. The 'encouragement' given here might be strengthened, perhaps by a requirement to include a Pacific researcher or to explain why no Pacific researchers are in the research team.

7.14. It may be helpful to have an example of what 'reciprocity' would look like in this context.

7.17. If there are any relevant documents researchers might go to, or or departments they might approach, for guidance on how to consult, it may be helpful to include this here.

### Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

8.3 - 8.23. For general feedback on 'Vulnerable Participants' please see our answer to Question 4 above.

8.10 The statement that researchers should only conduct research with children if comparable research with adults could not answer the same question is in direct contravention to the statement made in Research in children and young people (8.26).

8.15 Capacity is conflated with competence in the third line. These are different and should not be used interchangeably.

8.16 & 8.18 it is not just the complexity of the study that will have an impact on the capacity to consent, it is the accessibility of the information provided and so researchers must bear responsibility to ensure they provide information that is of appropriate format and ensure that support provided is of the appropriate type. ie reference the statement made in 9.2

8.24-8.29. In relation to several mentions of unequal relationships in these passages, it would also be worth clarifying when they are referring specifically to researcher/participant inequality, which is in many ways inevitable. Further, it may be worth emphasising that pretty much all relationships are unequal in some way, and it is more important to identify whether inequalities are creating problems than that there is an inequality in the first place.

8.28, 4th dot point. The clause about therapeutic benefit might be clarified: does it mean the researcher has to get assent for an entire intervention, or apply to particular parts of a broader intervention? Some components might meet this but not others.

8.29. It would be worth clarifying what it means to 'consider the views', here, or to give guidance on what to do if there is conflict.

8.30-8.36. Can some statement about what is required for or counts as “assent” be provided.

8.31, 4th dot point. It is unclear what would happen if a more mature child and parent disagreed about the research. Can something be stated about potential situations where, for instance, the child wants to participate but the parent or guardian does not want them to?

8.32. The final sentence here repeats the point made in the first paragraph.

8.35. We wondered if this point also applies to other groups or other vulnerable groups.

8.37. The wording here surrounding excluding women “because of their childbearing potential” could be confusing, since there are other reasons for historical exclusions, and this wording seems to come from the 1977 post-thalidomide FDA guidelines which excluded women from research on this basis. Maybe scare quotes and/or an explicit reference to these earlier documents/exclusions should be added here to explain the wording.

## Informed consent

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

### **Please outline your reasons why the section is or is not fit for purpose:**

Overall the standards do provide explanation and guidance about the role of voluntary informed consent in research. But there are some ambiguities and apparent conflicts that could be problematic. A key ambiguity is between the idea of informed consent as a dynamic process that continues throughout the life of the research, and as something that is ‘obtained’ when the participant signs the consent form. It is explicit in the introduction and at some other points, but these are in conflict with other places where the language could be modified to reinforce the ‘process’ nature of informed consent. This is particularly important in the context of contemporary and future research, which is likely to involve longer term studies (with more opportunity for withdrawal, or for gains in knowledge to make it appropriate to modify the protocol and therefore re-confirm consent), and also studies involving stored material in biorepositories.

Other ambiguities to be clarified are the circumstances under which the standards apply to non-research activities or activities that become research, eg where routine care leads to enrolment in a study. It might be worth reiterating somewhere in this section that the principles underpinning informed consent are equally applicable to some of these non-research activities and to innovative treatments. In these cases, even if formal ethical review is not required an appropriate informed

consent process should be followed that reflects the principles of mana tangata, transparency, individual autonomy and participant welfare.

It also feels as if the standards around informed consent are designed for clinical or life science research, and there is less fit to approaches and methods of social science research, for example. Note that this is not so noticeable in some other sections of the guidelines.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

The main discussion of ethical principles earlier in the guidelines covers both western bioethics and Maori ethical principles. Missing from the taxonomy of western ethical principles is any account of care or relational ethics. There is a discussion of Manaakitanga in Maori ethical principles, which seems to be the closest parallel. This absence is especially important since there may be cultural differences in the weighting of individual and collective risks/benefits, pertinent to consent to participate in research, that could best be addressed through a relational/care lens rather than the lens of autonomy or rights, for example.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

9.4. The ethical values informed consent promotes includes “promoting agreement with participants’ values”. It’s unclear what this means: agreement of what, or whom, with what; and what happens if participants’ values are not judged to be morally endorsable? It may be worth either explaining or checking the wording here.

9.8. It seems worth clarifying what ‘post-trial access’ means here. Both post-trial access to the therapy (where trial is of a therapeutic agent/intervention) and the post-trial storage and access to data should probably be covered in participant information.

9.16. Perhaps clarify here whether this relates only to procedures that depart from those that might be part of routine care.

9.20. The presence of a witness could raise similar confidentiality issues as an interpreter.

9.24. The phrasing is awkward and is better expressed elsewhere. Similarly, in 9.27, the wording “Researchers are responsible for ensuring that participants know that they are free to accept or decline an offer to participate in a study, and that they will not experience any disadvantage by making either decision” is awkward. Better would be 'not affecting quality of care' as used later on in the material on tissue, ie “will in no way affect the quality of a donor’s current or future clinical care”.

9.26. Typo in the final sentence : delete “being”.



9.29. It would be worth adding that this should also include any additional specific information relevant to the individual concerns/questions of that patient.

9.31. See comment in response to General Q3 about balance of information and practicality.

9.35. In relation to the phrase “indicate a lack of comfort with electronic media”, it may also be that for economic or other reasons, the individual or the community does not have access to it.

9.38. The point about disposal of a tissue sample requiring knowledge of whether there is a cultural protocol for its disposal is a good and important point, and likely not to be thought of by many researchers.

9.39. It is not clear what “third countries” means.

9.40. Regarding “The ethical acceptability of extended and broad informed consent relies on proper governance”: it would help to have some explanation on what is meant by proper governance.

9.42. “The deception or concealment will not compromise the relationship between the community and the researchers or research.” This should be extended to include participants who are also patients and those responsible for their clinical care.

9.48. “With integrated consent, the usual clinical discussion about treatment includes explaining that participants will be randomly assigned to one of the clinical options, but also informs them that their health data will be collected and used for the purposes of research.” This applies if the research has a randomised study design. The point could be more general e.g. “involves explaining details of the study, including (for randomised controlled trials) that participants will be randomly assigned to one of the clinical options...”

9.49 “However pragmatic such trials may be and even in low-risk comparisons of standard of care, significant practical and ethical tensions with integrated consent remain, particularly with respect to patient rights and individual autonomy.” These remaining concerns about autonomy and patient rights should be made clearer and linked to the stipulations at the end of this point.

“The discussion must clarify that the patient will still receive treatment if they choose not to participate in the research and it must distinguish between consent to treatment and consent to participate in research.” Note that integrated consent may be more appropriate/applicable for some of the non-research activities identified in the chapter on scope, such as innovative care that is not classified as research.

9.60 “These studies must have individual informed consent in order to meet New Zealand legal requirements.” Will there not be a problem with multicountry studies, where general waivers might be permissible at other sites but not in NZ? How should this be harmonised?

9.63 “ This method of consent reflects a balance between entirely waiving consent for use of data and requiring prospective consent, and is commonly used with registries.” Are registries considered as research? They may better understood as a monitoring/postmarketing surveillance activity: they are mentioned in the chapter scope under non-research activities, but only in terms of "pharmacovigilance" whereas registries can be used for all sorts of things and are often seen as a good option for devices. If this isn't mentioned in the scope chapter a clarification should be added.

9.65 “There are scientific, practical or ethical reasons why consent cannot be obtained.” There needs to be reasonably strong justification for practical issues being a genuine barrier to consent; that obtaining consent might entail more effort can't be taken as adequate justification, for example.

9.67 “Where populations have been excluded from research because they are unable to give consent, such as people in intensive care units, the severely disabled and those in emergency care, care or treatment options may be less strongly evidence-based because insufficient research about them is available.” This is an important point to make as it reflects a major ethical issue, to some extent counterbalancing ethical concerns about the absence of clear consent in these cases.

#### Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

The two-step approach seems to be reasonable and probably an improvement on the current situation. One concern would be not blurring the barrier between the 'steps', i.e. ensuring there isn't a gradual drift towards research that should be in the second category being classed in the first through changing ideas about what is 'more than minimal risk'. Another concern is who would be responsible for making the judgements about whether risk was minimal or not, or whether the risk/benefit ratio is 'at least as favourable to the participants' as alternative approaches.

#### Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

#### Research benefits and harms

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

10.3. While it is good that Māori principles are embedded throughout this document, , the extent to which they are integrated in various chapters differs. In this chapter and in the final three chapters the incorporation of Māori principles is quite thin and/or patchy.

10.7. the term 'well-being' could be used here to be more inclusive of the link between health and disability

10.10 Table 1

"Participants" - This does not include the long-term benefit of improved healthcare provision due to improved knowledge, for individual participants and communities. It may be some time in the future but there is still surely the expectation that those communities will one day benefit, and potentially individuals who took part in the original research, or members of their families.

"Researchers" - Knowledge advancement and learning is also seen as a benefit in itself to most researchers.

10.12 Table 2

"Social or Cultural Harms" - Loss of trust in clinical relationships or harm to the relationship between patient and doctor/healthcare provider is a type of relationship harm that is quite important in the context of health research; perhaps it could be explicitly listed here.

10.14. There seems to be no discussion of categories of risk more generally (cf the Australian National Statement) , though this term implies at least one other category.

10.16. This raises an issue of how and whether research ethics committees can make judgements about this (since it is presumably to be demonstrated to such a committee).

10.17, 2nd sentence: "A community's values and preferences are relevant in assessing potential benefits and risks of harm". This is relevant to research with some groups of disabled people where there is a history of abuse/exploitation in scientific or quasi scientific research.

10.19, 2nd dot point. We thought this needed some clarification. Of course it is important not exclude groups who might benefit from research on a particular disease or issue (e.g. research into heart disease shouldn't only be done on men and then applied to all) but we are not clear on why it should be required for every study to "address diverse health needs across different classes or groups". Sometimes a study in a narrow group is justified and can serve equity goals. for example, in the US it would be appropriate to study prostate cancer in African-American men as the disease is known to be different (e.g. more aggressive) and have worse outcomes than in other populations. The language used in relation to a similar point in 11.12-11.14 seems much clearer, and perhaps this could be rephrased in a similar way. It may also be useful here to include cross references in this section to relevant sections of the Types of Studies chapter.

## **Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

We would suggest cross referencing this chapter and/or subheadings of this chapter in other parts of the document that refer to recruitment, inclusion and exclusion criteria and sampling of minorities in research. These sections on the methodological underpinnings of recruitment and sampling strategies offer insight into why some populations might be deliberately over-represented or under-represented in a study in order to ensure both equity and methodological rigour. As such they provide much-needed explanation/elaboration of ideas that are gestured at elsewhere.

11.8. Perhaps replace “or resource” with “and resources”.

11.11, 2nd dot point. This might be altered to allow for multiple researcher(s) and sponsor(s).

11.16. We wondered if an equivalent statement about qualitative research would be helpful, though perhaps it would appear complex.

11.21. In many cases it will be rare to have a researcher who has all of these skills and resources. It might be better to talk of researcher teams.

11.22-11.25. We took this section to be about the peer review of research proposals, but these are guidelines on peer review for publications. Are the principles the same? It may be useful to clarify somewhere the connection between peer review of research proposals, peer review of papers reporting the study for publication, and ethics board review.

## **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

As noted above, there is a focus on a clinical model of healthcare research, ignoring qualitative or ethnographic studies. This is inconsistent with broader scope suggested in the earlier chapter on scope.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

12.1. The introduction could use some work. Maybe something as simple as changing the order of these sentences would be an improvement, for example:

1. The type of study researchers choose for their research should be the one best suited to answering the study question while meeting ethical standards.
2. These standards broadly categorise research as interventional or observational, while noting that many studies contain elements of both.

This does raise the question of what work the distinction is doing, if studies often contain elements of both: whether it tracks key ethical challenges, or whether it is a key distinction for methodologists, for example. Perhaps it is with adding something on this.

As we have discussed elsewhere, another issue here is how well qualitative or other non-clinical research studies will be understood in relation to this distinction. Possibly the introduction should mention (at least) some other key distinctions noted in the chapter, such as invasive vs non-invasive collection of data; low risk vs high risk conditions; therapeutic vs non-therapeutic; comparative vs non-comparative.

12.8. This listing seems quite limited and focused on a clinical model of healthcare research. Consideration of case series describing a new e.g. surgical procedure raise questions here. Are these observational, because the surgeon would have tried the procedure anyway, so that they do "not influence the assignment of any variable"? It may have many of the risks listed under "risks of harm in intervention studies" below.

12.13. We suggest adding cross-references to guidance documents, such as CEBM evidence levels material.

12.21. The clause "by chance" is awkward here, though included to recognise that only those randomised to the treatment arm within the study will receive it. We suggest removing "by chance" and replacing with "who are randomised to the treatment arm".

12.29 and 12.30 would be better referencing the more up-to-date terminology of 'co-production' which is a broader explanatory framework to explain the process being referred to here. A reference to this kind of approach which encompasses activities from question identification through research design, data collection, analysis and interpretation would give clarity to this section.

There is also a concern here that the methodology of co-design or participatory research is being confused with the methodology of 'action research' – this is an established and well documented research design in which research activities are iterative and responsive.

12.32. While such trials do currently occur more frequently in oncology, they are not exclusively used there. We suggest broadening this point.

12.36. We wondered whether the Standards will include appendices with examples of participant information sheets etc? This could be a useful way of illustrating how all the detail required by the standards can be delivered in an accessible and not overlong information sheet written in lay language.

## Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

13.14. Again, while we applaud including these less tangible or instrumental aspects of research practices in the Standards, but it does raise difficult questions about how researchers can be expected to assess a relationship as 'meaningful' and relate it to 'the ethical tenor'. We suggest that some discussion about terminology like this could be helpful.

13.19. Can this point be broadened to include disability, and not just poor health.

13.19, 2nd dot point. We suggest considering rewording "the worst off" to, for e.g., "a population with serious unmet needs." We wonder whether research for e.g. a rare condition might be the sort of thing it is hard to raise adequate funds for, has high acceptability of charging participants and can meet the other conditions, but where it is unclear whether those who would benefit are the "worst off in society", depending how this is defined.

13.19, 4th dot point. The word "unlikely" in the second sentence here seems to be included more for emphasis than accuracy. We suggest rephrasing.

13.25. It may be worth clarifying how the prohibitions on deception here relate to research that is deception by design, and cross-referencing to the section on that.

13.27. We suggest omitting "eye catching". There seems no reason a research advertisement can't be eye catching as long as the visual elements aren't misleading or problematic. E.g., an image of an elite athlete in an ad for a knee replacement study might be a problem, but bright colours need not be.

13.30, 2nd dot point. Research may sometimes be conducted via another route but also on social media (e.g. focus groups). Perhaps that should be discussed here alongside recruitment and/or cross-referenced to another section.

13.48, Table 3. We found this table unclear, partly due to its use of the terms "unlikely" and "maybe". The footnotes do clarify the meaning, but this makes the point of the table less clear.

13.63. It is worth emphasising this reference to "health and safety" could include not just the health and safety of participants, but could extend to others. The participant information sheet might also include information on the conditions under which privacy and confidentiality may be overridden.

13.69 The 'should' rather than 'must' here is presumably to acknowledge that pragmatically, some important research may never take place unless sponsored by a body that does impose such restrictions for commercial rather than ethical reasons, e.g. a company. Perhaps this could be clarified.

13.72. "The same study" may be too restrictive here and might be altered to "studying the same intervention".

13.75. Deficit thinking is expanded upon but victim blaming is not. Can victim blaming be expanded on too?

13.78-13.79. In the genetic context there is a lot of debate about this, so the statement here about duty/responsibility is too sweeping. The debate usually is about (genetic) variants of unknown significance. This is becoming more of an issue as sequencing becomes more widespread. However, researchers may not know which findings are "clinically actionable".

### **Charging participants**

**Please outline your reasons:**

#### **Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

14.2 To our knowledge the phrase 'social equipoise is not standard, so it may be worth elaborating on this.

14.13. It is worth noting that the stipulation "and the disclosure has first been justified to an ethics committee" may not possible if the threat really is "imminent".

14.17. We suggest adding a cross-link to the section on data linking to indicate that potential risks of re-identification associated with data-linking and big data.

14.23, first dot point. This is unclear - where should it be specified? In the consent for the original research? The hyper link provided for "specified" does not clarify this.

14.43, Table 6. Seeming typo: 'dignitary harm'.

14.52. This list seems repetitive of material covered earlier in the chapter. Perhaps this is appropriate as it is outlining what needs to be covered in documentation relating to the research, but perhaps there is a way of avoiding the repetition, e.g. by stating that information pertaining to all relevant sections of this chapter must be described in the research protocol.

Big data and new ways of using data

Not Answered

**Please provide feedback:**

### Databanks

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

14.61. This could further clarify the researcher's responsibilities. For e.g., should the researchers be expected to find out what they can about the particular databank, including (if possible) whether people are likely to have been aware their data was submitted, etc.?

14.62, 3rd dot point. There are specific issues to do with identification of family members via genetic/genomic databases, that should be highlighted. The distinction between governance of future access for other health research, and future access for other non-health research reasons, should also be highlighted.

14.62, 8th dot point. Here perhaps some of the Māori values e.g. whakapapa and whānau should be explicitly mentioned again in terms of disclosure including consequences for family and community?

14.62, 14th dot point. We are not sure that transparency should be part of the same point as participatory engagement. Transparency is important irrespective of the degree and nature of participatory engagement, and while the two things can overlap they can also be justified separately.

### Human tissue

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**



The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Some inclusion of Maori values might be relevant to include in this chapter, perhaps in both the commentary and standards.

One additional potential ethical consideration is the specific or different risk/concern associated with this particular type of tissue used in a research setting. For example, if a study is testing personalised treatments comprised of autologous tissue from people with a particular genetic makeup/background, the risks will be different from those of research involving treatments from non-autologous tissue.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

15.1. The last sentence should make a contrast with chapter 16 (as well as chapter 17).

15.3. One additional potential ethical consideration is the specific or different risk/concern associated with this particular type of tissue used in a research setting. For example, if a study is testing personalised treatments comprised of autologous tissue from people with a particular genetic makeup/background, the risks will be different from those of research involving treatments from non-autologous tissue.

15.4. In first sentence, suggest replace "especially" with "including", or rephrase. Māori concerns are especially important in NZ context, but other groups may hold equally strong beliefs.

15.6. We suggest a cross link to Chapter 17.

15.25. We suggest rephrasing 'counsel' in the first sentence, to avoid any suggestion researchers are expected to give emotional advice.

15.28. This phrase could be read as implying that these are only problems if the disease doesn't develop in the person. We suggest rephrasing, perhaps to 'Whether or not the disease develops...' or 'Even though the disease may or may not develop...'

15.31. Perhaps this should include 'and tissue' in addition to 'stored data'?

## **Biobanks**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Again, Māori principles seem not to be addressed in this chapter as they are in other chapters.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

It may be worth including something in the Standards on the commercial use of biobanks.

### **Research with stem cells**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Again, Māori principles are not addressed in this chapter, except on one or two occasions under the commentary.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

17.15. If this is an exception to previous discussion, which allowed paying to participant in some circumstances, perhaps it should be mentioned in those discussions.

17. 22. We suggest considering cross-referencing here to material on p.112 re. imported tissue?

Response number	63
Name	[redacted]
Organisation	New Zealanders for Health Research
Role	[redacted]
Interest group	Researcher / consumer / industry
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

**Please outline your reasons:**

The results of the 2018 New Zealanders for Health Research (NZHR) Roy Morgan Research public opinion poll indicate that New Zealanders value and are positively disposed to participating in health research. 82% said that they were willing to share personal health information to advance medical research; 69% believe that health research can contribute to reductions in health care costs; 79% said that is important for New Zealanders to be able to participate in clinical trials; 83% said that they would be willing to participate in a clinical trial of a new medicine if they had a condition it might be able to treat; and 62% percent agreed that participating in clinical trials for new medicines is as important as donating blood.

NZHR believes that it is important for this good will to be respected and preserved by ensuring that participants' rights are fully respected and maintained. This will assist in ensuring that health research is viewed positively now and into the future, will contribute to the generation of excellent, impactful research, and will ensure that New Zealand's good reputation for health research is maintained both domestically and internationally.

NZHR welcomes the introduction of the revised standards and believes that overall they are fit for purpose.

The standards are applicable to all types of health and disability research  
Agree

**Please outline your reasons:**

The standards balance protecting individuals with the realities of conducting research  
Agree

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research  
Agree

**Please outline your reasons:**

Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:**

Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Neutral

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Neutral

**Please outline your reasons or suggested improvements:**

The distinction between research and non-research activities is inherently problematic. If there's any doubt, or if the activity requires identifiable patient consent or participation, or could impact on patient care or well being, then the activity should be considered to be research and be subject to ethical review.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

Para 4.19

Except for minor innovations innovative practice should always require research and evaluation

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Not Answered

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

### **Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:** Para 11.11

The protocol should also require a description of the potential impact of the research and how results are expected to be disseminated and translated into policy and/or practice

Para 11.21

The list of appropriate skills and resources should also include a requirement that skilled and experienced and/or fully trained interviewers are employed where field studies are undertaken involving direct communication with study participants.

### **Types of studies**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

**Charging participants**

**Please outline your reasons:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

NZHR has concerns that this section may prove to be unworkable. As it is currently worded it does not provide sufficient guarantees to trial participants that if something goes wrong they will be adequately compensated in a timely way, and we are not convinced that third party insurers will always be fully willing to compensate study participants, or to quickly settle any claims, despite the best intentions of the funders and sponsors of any given clinical trial.

Furthermore we think that the potential solution of requiring commercial trial funders to underwrite any compensation costs, so that they, rather than study participants become directly responsible for recouping compensation costs from the insurers, risks disincentivising commercial investment in clinical trials.

NZHR believes that the best solution will be for ACC to extend its cover to clinical trials participants. We appreciate that this is beyond NEAC's scope. If another acceptable mechanism is not identified in the final version of the standards NZHR will actively advocate for ACC to extend its cover accordingly.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:** see above

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:** see above



Response number	65
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Research
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

The standards are applicable to all types of health and disability research  
Agree

#### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Strongly Disagree

#### Please outline your reasons:

Section 9.60 Clearly outlines that New Zealand has no legal mechanisms for a 'general; waiver of consent.

This law is prohibitive to the conduct of research in setting whereby there is no ability for a patient to consent.

Moreover, in line with the commentary provided by NEAC in clause 9.67, we surmise that it is unethical to exclude a population from research because they are unable to give consent, such as people in intensive care units, the severely disabled and those in emergency care.

Exclusion of such populations means they are less-likely to have the benefits of research, such as evidence based care, that are afforded to other populations that can consent. Therefore, it is crucial for NEAC and the MOH to engage the updating of such laws that are "unethical".

The standards support researchers to navigate ethical challenges in health research  
Agree

#### Please outline your reasons:

#### Overall do the Standards?

Standards - safeguard the rights and interests of participants in research: Agree

Standards - promote high-quality ethical research for social, cultural and economic wellbeing:

Agree

**Standards - reflect the principles of the Treaty of Waitangi:** Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

There is discordance regarding the legal guidance provided in the 2012 guidelines versus the current draft provisional guidelines. In the 2012 guidelines, section 6.29, there is clearly provision to enable the undertaking of interventional studies when a participant cannot consent, provided that the study meets ethical standards (best intervention and equipoise). Conversely in the draft 2018 guidelines, section 9.60, it is stated that “New Zealand has no legal mechanisms for a ‘general’ waiver of consent, as is available in other countries”.

We strongly suggest that the 2018 interpretation of the law by NEAC is reviewed to ensure that this is correct prior to finalizing the guidance provided regarding this.

If the 2018 interpretation of the law is correct that “New Zealand has no legal mechanisms for a ‘general’ waiver of consent, as is available in other countries” then the guidance provided in sections 9.60 and 9.66 through 9.71 provides clarity on the current legal and ethical considerations for those patients who cannot consent.

St John and Auckland University of Technology are in strong agreement with NEAC, section 9.69, that (if the legality has been interpreted correctly) the current legal imperative of requiring informed consent is restrictive and prohibits some participants from accessing health research.

Moreover, in line with the commentary provided by NEAC in clause 9.67, we surmise that it is unethical to exclude a population from research because they are unable to give consent, such as people in intensive care units, the severely disabled and those in emergency care.

Exclusion of such populations means they are less-likely to have the benefits of research, such as evidence based care, that are afforded to other populations that can consent. Therefore, it is crucial for NEAC and the MOH to engage the updating of such laws that are “unethical”. A clear example of this is the PARAMEDIC2 trial where it is unknown as to the benefits, or harm, of the use in adrenaline in cardiac arrest. Without such trials, the precedent for the use of adrenaline in cardiac arrest cannot be established.

## **Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

Response number	67
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Commercial Sponsor
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

**Please outline your reasons:**

The standards are applicable to all types of health and disability research  
Agree

**Please outline your reasons:**

The standards balance protecting individuals with the realities of conducting research  
Agree

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research  
Agree

**Please outline your reasons:**

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:**  
Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Neutral

**Please provide feedback with reference to the paragraph(s) in question. :**

Section 6.19: In the case of international clinical trials it will often be the case that the protocol is designed overseas and is being applied to a New Zealand context. In such cases it is important to try to adapt the protocol to the New Zealand context as much as possible.

It is important to retain the first sentence in section 6.19 and acknowledge that for large, multinational studies the opportunity to adjust protocol requirements to fit a specifically New Zealand context will be limited. Emphasis on the adaptability of protocols to a New Zealand context may have the effect of making it more difficult to place international studies here.

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

Please see comments below.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Section 18.3: For commercially sponsored research to be conducted ethically, researchers must satisfy an ethics committee that participants have access to compensation for injury to at least the equivalent of any Accident Compensation Corporation (ACC) compensation that would be available to them if they had been injured in research that was not commercially sponsored. Such compensation includes earnings-related compensation and compensation for surviving partners, children and dependants in the event of death ('alternative compensation'). This must include 'no-fault' compensation which is available to persons participating in non-commercial trials.

We strongly agree that New Zealand participants should have appropriate access to compensation when unable to access ACC, however we are concerned that use of 'must' in the final sentence - 'must include 'no-fault' compensation' - may prevent NZ patients having access to commercially sponsored clinical trials. In practice we are not insured in the case of investigator malpractice. Indemnity provided to the healthcare professionals responsible for trial conduct is dependent on adherence to substantive protocol requirements, in particular appropriate screening and inclusion of eligible patients (ensuring patient selection excludes at risk patients as described in the protocol), treatment management as per protocol (following correct dosing and where necessary

dose reduction or cessation instructions) and management of adverse events. The protocol is designed to answer a study question and also to ensure the safety of trial participants through safe trial practices. The current national indemnity agreement conditions point to the need to meet protocol requirements as a prerequisite for indemnity coverage.

Regarding equivalent compensation rates to ACC coverage; it would be advantageous to know what cover ACC provides as 'alternative compensation' for medical misadventure cases, so sponsors know what is being asked of them and can therefore provide informed feedback. This is potentially a significant and impactful change to current compensation for injury cover.

Response number	68
Name	[redacted]
Organisation	[redacted]
Role	Clinical Advisor - Research
Interest group	Researcher
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

#### Please outline your reasons:

Comprehensive coverage of the issues, and generally well articulated. The flow from principles to standards is good, but exactly how the commentary sections fit in is unclear. They often have very important information, and sometimes even use the word "must". Are such statements to be considered equivalent to the standards, or something lesser? This needs to be clearer.

Some statements relating to the law go beyond what is appropriate for this document. The principle (as in 3.3) that "researchers are responsible for meeting all relevant domestic legal requirements and international conventions when conducting research" is correct. However, the standards should not provide guidance on legal matters, but rather identify areas where there may be a difference between the standards and the law, and (re)emphasise that researchers should seek legal advice regarding meeting their legal responsibilities.

The inclusion of innovative treatment (4.7 - 4.22) does not fit very well in a "research standards" document, as this is primarily an issue of clinical care and consent for treatment. In my opinion it would be best in a separate guideline. The standards would still apply to any research conducted in relation to an innovative treatment.

The standards are applicable to all types of health and disability research  
Strongly Agree

#### Please outline your reasons:

I have not identified any significant gaps.

The standards balance protecting individuals with the realities of conducting research  
Strongly Agree

#### Please outline your reasons:

The balance has been placed correctly, with the default position in favour of protection, but recognising that in exceptional circumstance alternative approaches may be appropriate and only within well-defined boundaries which must be shown to be met.

The standards support researchers to navigate ethical challenges in health research



Agree

**Please outline your reasons:**

Mostly this is true, but the document is long and complex. When finalised, simpler versions, flow charts etc may be needed to assist researchers who may not be familiar with the standards and their application.

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Strongly Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Strongly Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

**Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

The draft standards appear to be comprehensive.

**Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Strongly Agree

**Please outline your reasons:**

The risk-based approach in the draft standard, applied irrespective of the research design, ensures that participants in all types of research receive equal protection in circumstances of equal risk.

**Scope of the standards and non-research activities**

Is the scope of the document clear?

Agree

**Please outline your reasons or suggested improvements:**

I support the concept that ethical standards apply all activities.

The broad definition of research (4.3) covers most of the activities considered to be "non-research" in 4.6. This is confusing; perhaps the distinction is better described as when a research-like activity (broadly defined) requires (or does not require) formal Ethics approval.

For example, "generating new knowledge" from "data" will apply to most types of audit.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

Is the use of the word "must" appropriate in 4.6; is "should" better?

Audit definition (4.6) needs to be able to include exploratory investigations by providers where there are no reference standards and/or where the intention is to track performance over time (i.e. the comparator is internal not "explicit").

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Clear outline of principles. How Te Ara Tika principles are incorporated has been well articulated.

Possibly could benefit from one or two other examples when an ethical decision requires the balancing of conflicting principles.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Should the lines joining the principles in Figure 1 extend to "Mana" and "Justice"?

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Generally good. See note below regarding 6.12

Conflict between 6.7 and 6.24 regarding "must collect" ethnicity vs "unless justified why not necessary"

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

The consultation levels in Box 1 are appropriate.

The phrase "particularly for research involving Maori" in 6.12 seems to be referring to research with a particular focus on Maori (collective/s or Maori-centred), rather than the individual participation of Maori in a general population study.

### **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Generally good . Should the title be "Special categories of participants" or "Vulnerable participants"?

It is a bit unclear with layout/headings if Children and Young People and Women are sub-categories of vulnerable participants (8.10, 8,11) or categories of participants.

Minor clarification issues as below.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

8.1. Should "harm" be "being wronged or harmed"?

8.2 Ambiguous use of the "they"; needs to be clearer that a group benefit is acceptable.

8.10 The standard is not "could not answer", but "could not adequately/appropriately answer". Comparable research in adults may provide some sort of answer.

8.16 Is an exception to determining capacity when incapacity is a necessary attribute of the study population? 8.40 Should read "if they become pregnant..."

## **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The concepts of integrated consent and abbreviated consent are helpful.

I strongly support the proposed two-step approach to "non-consensual research with adults who cannot provide informed consent" (9.6, 9.90).

The interpretation of the law to provide specific advice about legality regarding various possible approaches to consent (9.6, 9.69, 9.90) is not appropriate for this Ethical Standards document. The Standards should be clear about the ethical approach, and limit comment to the "researchers must comply with the law" principle as in 3.8, 9.75, 9.82 and 13.2. If this is done, then the Ethical Standards could support a defense of actions (consistent with the Standard) as being "reasonable in circumstances" as allowed for in Section 3 of the Code of Rights.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

Does not address the issue of the data sharing requirements now in place for most major journals i.e. that plan must be in place to allow other researchers access to anonymised individual patient data for further analysis. This is now an expectation for most forms of clinical research.

Although the concept of a "databank" could cover this, I think that it warrants its own section in Chapter 14 and specific mention in this informed consent chapter.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

9.9 "Any modification to the informed consent process..."?

9.16 is problematic as it could be interpreted that screening for study eligibility using existing clinical data requires consent. Needs to focus on additional study-specific measures to assess eligibility. Inconsistent with 13.21 and 13.22.

9.24 "Retribution" is not the best wording! Suggest "...without disadvantage"

9.49 "...such trials may be and even in low risk..." does not make sense

9.72 Suggest reword as "The research question cannot be adequately addressed by conducting

the research in a consenting population" 9.86 Change "...not able to identified.." to "...not able to be

identified, or if identified, not available,..."

**Research with participants who are unable to consent**

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

The approach to the ethics in the draft Standard for research involving participants who are unable to consent is excellent and is stated clearly.

As noted above, in my view the Standards should not provide legal advice. The Standard should state what is considered ethical, only note that researchers should be aware that in this setting that there may be a conflict between between meeting the ethical standard and regulatory compliance, and that as indicated in

3.8, regulatory compliance is the responsibility of the researcher.

**Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

Yes, the suggested approach is appropriate.

**Research benefits and harms**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Covers the issues appropriately

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

Table 2 - Privacy harms should be "Disclosure of private information", not just identification

10.16 - perhaps expand the concept of "people with cancer" to "people with cancer with limited treatment options"

## Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

## Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Generally good, but see below for some specific issues.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

12.3 fails to allow for "invasive means of collecting data" without individual consent (12.3). This suggests that it is not ethical for additional (research only) low-risk invasive tests participants who cannot be "informed of the risks". Examples where I would consider it ethical in intensive care include additional blood sampling from patients with a blood sampling cannula already in place, or additional respiratory secretion samples from a patient receiving invasive mechanical ventilation.

This is inconsistent with 15.5 which allows for a waiver of consent for the collection of tissue samples and also with the proposed standard (9.90) where minimal risk research with benefits to the group to which they belong may be ethically undertaken without participant consent.

I suggest that ethics committees could be permitted to approve a waiver of consent for such low risk research, including if appropriate the requirement that a relative/friend/whanau agrees that the patient would be not object to such samples been taken.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

12.6 - the control group in an intervention trial may receive no treatment or an inactive placebo where there is no "established effective intervention". Should the phrase "(if one exists)" be included, or does "...justify a different approach" cover this issue?

12.4 Reword as "...allocation concealment, blinding of interventions and outcome assessment (where feasible)..."

12.39 This needs to be clearer as to what is the ethical rather than perceived legal standard. Is the ethical standard really that "researchers must get informed consent from all participants in a CRT"? It may well be justifiable ethically not to seek individual consent in a cluster randomised trial; researcher would need to argue the case for this to the HDEC. Alternatives such as notices at the study site, opt-out processes etc should be mentioned, as well as a full waiver. As suggested in the informed consent section feedback, the possibility that this may not be consistent with current regulations should be the researchers responsibility.

**Research conduct**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Generally good. Some specific comments as below.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

13.21 the final "dot point" should add "...except for the minimum information necessary to contact a potential participant or to undertake an assessment of eligibility"

13.22 - fine, but note that 9.2 currently restricts "personal data collection" for eligibility screening without consent.

13.48 - the better term is "Data and Safety Monitoring Committee", as often individual safety reports (not just aggregated data), especially in early phase trials, are reviewed by these committees.

13.51 - there should also be an adverse event plan for observational studies with a risk of adverse event e.g. invasive tests. **Charging participants**

**Please outline your reasons:**

Yes, the proposed standard is appropriate.

**Health information**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

Generally good. Some specific comments below.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

14.22 does not address the issue of data from participants who were unable to consent for themselves at the time of enrolment, and remain incompetent or die before consent for data use was obtained. Prohibiting the use of this data overseas would seriously weaken the scientific validity of NZ's contribution to international multi-centre research.

14.37 - spelling of "Researchers"

Big data and new ways of using data

Agree

**Please provide feedback:**

Yes, balance is appropriate.

**Databanks**



The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Should there be a section here on the new medical journal requirements for data sharing of anonymous individual patient data from published studies?

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

14.62 and 14.63 - Do these sections need to address the contribution of NZ data to international benchmarking registries (e.g. many are joint ANZ registries) where we do not have control of the use of data for research (other than ensuring there are appropriate governance processes) ?

## Human tissue

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Not Answered

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Not Answered

**Please provide feedback with reference to the paragraph(s) in question:**

15.1 Perhaps the definition of "human tissue" should be in the body of the text rather than in a

footnote. 15.15 Inconsistent with 12.3

## Biobanks

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Should the Standard include some discussion of overseas biobanks?

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Research with stem cells

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Compensation for commercially sponsored intervention studies

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

Broad principles are OK, but some of the detail could be better.

As a general comment, the local examples of delay in settlement arose from uncertainty about causation (i.e. did trial participation cause the harm or was it the participants underlying disease), which would not be avoided under ACC which also takes a similar approach in that the "treatment" must be the cause of the injury, not the disease.

Would NEAC be prepared to suggest that it would be preferable ethically if injury arising from participation in commercially sponsored research could be covered by the ACC scheme?

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

18.5 Should this be all types of clinical trial? A single trial would never include "early phase" and "Phase IV".

18.6 Is the requirement for early independent mediation actually enforceable? If not, perhaps change to "should".

18.7 Include a statement such as "how the investigator and their employer would support the participant in making a claim"

18.3 is contrary to 18.7 with regard to "must include 'no-fault' compensation" vs a requirement to describe how it is not 'no-fault'. Suggest remove last sentence from 18.3.

18.11 This appears to be out of place. Isn't the need for a card related to clinical care issue, and so should be mentioned in the "trial conduct" section? I cannot see any benefit in the ACC cover issues being on a trial card. If there is need for urgent medical treatment, ACC are only involved in treatment funding when it is more than 6 weeks after injury.

Response number	69
Name	[redacted]
Organisation	[redacted]
Role	Clinical Trials Manager
Interest group	Researcher
Publish response	You may publish this submission

## Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

### Please outline your reasons:

I think that combining the guidelines for observational and interventional research into one set of standards is a significant improvement as it better frames the ethical considerations that are important in the conduct of all kinds of research (such as the risk: benefit ratio) rather than appearing to draw a distinction in terms of ethical considerations by having separate guidance documents. For instance research that is observational can at times present significant risk and conversely research that is interventional is often very low risk.

By presenting the document as a set of standards rather than as a guideline, it also reinforces the importance of adherence to these "rules" for ethical conduct.

The standards are applicable to all types of health and disability research  
Agree

### Please outline your reasons:

The standards balance protecting individuals with the realities of conducting research  
Agree

### Please outline your reasons:

The standards support researchers to navigate ethical challenges in health research  
Agree

### Please outline your reasons:

### Overall do the Standards?

**Standards - safeguard the rights and interests of participants in research:**  
Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Strongly Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

**Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

In general they do adequately cover the ethical challenges that are present in health and disability research; however, there are some areas where the standards are probably insufficient to meet both current and future health needs in NZ. The particular areas where I think there is some deficiency in coverage are:

1. Research in ethnicities other than Maori and Pacific - NZ is already a very diverse population in our larger centres; the proportion of NZ residents and citizens who identify as being of an Asian ethnicity (e.g. Chinese or Indian) is significant and is projected to overtake Pacific ethnicity in the relatively near future. There are already signs of particular health challenges for these ethnicities for instance: recent research in maternal and neonatal outcomes indicates that Maori, Pacific and Indian mothers and babies have poorer outcomes than women and babies of other ethnicities in NZ. Also there are known to be distinct challenges in mental health management associated with cultural differences including attitudes or beliefs related to religious practices and values outside of a Western-Christian framework. Addictions (problem gambling) is emerging as a significant health issue in Chinese and other East Asian families.
2. Research in adults who are unable to consent due to chronic diminished mental capacity/cognitive function (e.g. dementia, post-stroke etc), in mental illness/psychiatric care, or intellectual disability. The new standards confront the challenges in research in incompetent adults in acute medical situations (e.g. intensive care and emergency medicine) but somewhat skirt the challenges of research in indications associated with neurological degeneration, dysfunction due to neurological injury, or neurological developmental deficit from birth. As an aging society and a society with high rates of risk factors for stroke and dementia, increased knowledge and diagnosis of Autistic spectrum disorders, mental illness and foetal alcohol syndrome, it is imperative that we accept the need to conduct therapeutic research in these areas and meet the challenge of devising appropriate ways to conduct ethical research in these patient groups.

**Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

Please see comments for Q1 of the fit for purpose section.

**Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

The sections on innovative practice are useful. It would also be useful if this section discussed the issue of "case studies" in research.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

**Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Figure 1, paragraph 5.6 which depicts the partnership of principles between Te Ara Tika and traditional bioethics principles is very helpful. However, paragraphs 5.9 and 5.11 whilst useful discussing the way in which these principles may be jointly applied or may in fact be in conflict seems unfinished in that it does then cross-reference these principles to the legal frameworks of NZ that deal with human rights (e.g Human rights act etc).

**Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

The degrees of consultation outlined in box 1 of paragraph 6.20 are helpful, in terms of providing some clarity around the relativity of what level of consultation is appropriate for the 4 "levels" of Maori involvement in research (ranging from research that does not involve Maori to Maori-centred research and Kaupapa Maori research). However for the 2 categories "research that does not involve Maori" and "research involving Maori" it is not clear to me, outside of the setting of a DHB or University, i.e. in private medical/research practice what would be considered acceptable as appropriate "Institutional review" or "Institutional ethics approval" . Additionally it would seem to me that "research involving Maori as a collective" (rather than as individuals) actually warrants a separate section within box 1 and that the minimum expectations for consultation in research involving Maori as individuals and research involving Maori as a collective should be more clearly delineated as being different.

### Categories of participants

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Please see my comments concerning the coverage of the guidelines.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Informed consent

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Paragraph 9.19 - it would be helpful to have additional clarification about who can be an appropriate intermediary for participants who are not fluent in English (i.e. the acceptability of relatives etc acting in this capacity is always a contestable issue when ideal world perspectives and realities/practicalities often clash). Paragraphs 9.22 and 9.23 appear to be somewhat contradictory - 9.22 appears to be saying that there is not a requirement to re-consent in longer running studies if there has not been a significant amendment where as 9.23 appears to be suggesting that verbal re-consent would be appropriate in studies where there are multiple participant-researcher interactions. As longer running studies will usually involve multiple participant interactions it would thus seem that verbal re-consent is required.

Paragraph 9.50 indicates that for integrative research verbal consent may be allowable provided the consent process is appropriately documented - however when the realities of getting a clinician/health practitioner to properly document the consent process are considered in the light of a busy workforce who are primarily attending to the participants as part of providing routine healthcare it would seem to be an inevitability that there would frequent failings of documentation and potentially frequent failings of the consent process- all parties involved in the research are likely to be better off if the process includes collection of written consent from the participants.

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

Please see comments in the coverage of the standards section. Further discussion and clarity around research in adults with long-term/permanent intellectual or neurological health conditions and disabilities or with mental health issues is necessary.

**Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

**Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**



There is a lack of clarity in the standards around appropriate provision of compensation for participants who are harmed by participation in observational research. Additionally the standards are directed at researchers who are responsible for ensuring that Sponsors of commercial studies have appropriate insurance cover in place but there is a paucity of guidance in the standards to ensure that researchers are empowered to ensure that they can require appropriate levels and types of insurance cover i.e. insufficient detail of minimum policy coverage standards or cover limits.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

It will be extremely difficult for researchers to address the requirements of paragraph 18.7 and address all these points truthfully and still recruit participants into earlier phase studies where the risks are great given the lack of firm NZ regulation etc to enforce compensation standards by commercial sponsors...

Response number	70
Name	[redacted]
Organisation	[redacted]
Role	Science and Technical Advisor
Interest group	Industry
Publish response	You may publish this submission

### Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

**Please outline your reasons:**

The standards are applicable to all types of health and disability research  
Agree

**Please outline your reasons:**

The standards balance protecting individuals with the realities of conducting research  
Agree

**Please outline your reasons:**

The standards support researchers to navigate ethical challenges in health research  
Strongly Agree

**Please outline your reasons:**

**Overall do the Standards?**

**Standards - safeguard the rights and interests of participants in research:** Strongly Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**  
Agree

**Standards - reflect the principles of the Treaty of Waitangi:** Agree

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**  
Strongly Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**  
Agree

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Agree

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Agree

**Please describe the ethical challenges that are missing:**

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

Overall, the merging of both observational and interventional guidelines is beneficial and makes clear the standards that apply to each type of research.

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Agree

**Please outline your reasons or suggested improvements:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question. :**

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

Paragraph 6.19 states that “in the case of international clinical trials it will often be the case that the protocol is designed overseas and is being applied to a New Zealand context. In such cases it is important to try to adapt the protocol to the New Zealand context as much as possible.” The acknowledgement in section 6.19 of the realities of international clinical trial design is appreciated. In the case of international clinical trials, it is anticipated that engagement and involvement with Maori will be achievable at the New Zealand investigator and clinical trial site level. However, adaption of international protocols may be limited or not possible in some cases. Further guidance to follow for international trials would be valued. Furthermore, we are concerned that the current

wording regarding adapting protocols may be unintentionally perceived as a barrier to involving New Zealand in international clinical trials. Overall, we agree that the section is workable. However, we recommend further detail be included on this topic.

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Disagree

**Please provide feedback with reference to the paragraph(s) in question. :**

We believe additional clarification is needed regarding requirements for consultation with Maori for commercially sponsored research, specifically for international clinical trials. Paragraph 6.12 outlines that consultation “with Maori at an early stage in the design of the study is preferred” but it also acknowledges that in practice researchers often conduct consultation after research protocols have been set. Following on, Paragraph 6.19 states that “in the case of international clinical trials it will often be the case that the protocol is designed overseas and is being applied to a New Zealand context. In such cases it is important to try to adapt the protocol to the New Zealand context as much as possible.” Furthermore, In Box 1 it explains that consultation with the collective is to occur at the earliest stages of development of the research design. There appears to be variation between the requirements set in these sections so it not clear what level of Maori consultation is required for international trials. We believe this needs to be clarified further.

Box 1 outlines that for research involving Maori, a minimum expectation is that “collective consent is obtained from the appropriate mandated leadership/governance entity for the named collective.” There is a lack of detail regarding this requirement. For example, it is not clear which stage of development collective consent must be obtained. Is it to be obtained at an early stage of research design? Or prior to the New Zealand approval of the trial? Or at the time of participant recruitment and participant consent? Or at another time? Further detail regarding collective consent would help to clarify what is required.

## **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline your reasons why the section is or is not fit for purpose:**

In the previous section, Research involving Maori, paragraphs 6.24 – 6.27 outlined principles for ethnicity data collection. We query whether similar paragraphs should be present in the section regarding Research involving Pacific people.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

We commend and support NEAC's forward-thinking and patient-centric principles regarding the rights of research participants and in particular potentially vulnerable people. We believe the section is comprehensive and provides useful guidance for researchers regarding research involving potentially vulnerable people.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

We believe the section is comprehensive and provides useful guidance for researchers regarding research involving potentially vulnerable people.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Strongly Agree

**Please outline your reasons why the section is or is not fit for purpose:**

We commend and support NEAC's forward-thinking and participant-centric approach regarding informed consent for research. We believe the section is comprehensive and provides useful guidance for researchers seeking consent for research in a diverse range of circumstances.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Strongly Agree

**Please outline any missing ethical issues or principles:**

We believe the section is comprehensive and provides useful guidance for researchers seeking consent for research in a diverse range of circumstances. We commend and support NEAC's forward-thinking in setting principles for situations such as the duration of consent, consent for future unspecified use of tissue, databanks, abbreviated consent in medical emergencies, research with adults who cannot provide informed consent and additional protections.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Research with participants who are unable to consent

**Given the current legal environment, does the ethical guidance provided in the draft**

**standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes: Deception**

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

### **Research development and design**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Regarding the requirement for peer review of research proposals, we seek further clarification on the level of independence required of reviewers. Paragraph 11.23 states that "Reviewers must be sufficiently independent to be able to conduct their review of the study without bias". Commercially-sponsored research proposals go through rigorous internal review processes by suitably skilled reviewers (for example, but not limited to medical, scientific and statistical specialists). Review processes for commercially sponsored research proposals may not be conducted by external peers. Rather, independent review of scientific aspects will be completed by Medsafe and independent ethical review will be completed by the Health and Disability Ethics Committees (HDEC). This process has been accepted previously. However, it is not clear whether this satisfies paragraph 11.23 of the Draft National Ethics Standards. Therefore, further guidance and clarity regarding independent peer review for commercially-sponsored research would be valued.

### **Databanks**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

We commend and support the forward-thinking guidance and principles regarding use and storage of data, and databanking.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Human tissue

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

We commend and support the forward-thinking and comprehensive guidance and principles regarding use of human tissue for research.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Biobanks

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

We commend and support the forward-thinking guidance and principles regarding use of biobanking.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

Section 18.3 outlines requirements for commercially-sponsored research, compensation for injury must be at least equivalent of ACC compensation that would be available to them for non-commercially-sponsored research. We agree with the principle. From a practical perspective we ask for further guidance on how to meet this requirement, specifically how to determine the level of compensation that is at least equivalent to ACC compensation.

Furthermore, we would like some clarification in the ethics standards of what standard should be followed for any injury to a patient that would not be covered by ACC in non-commercially-sponsored research, such as emotional distress.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Disagree

**Please outline any missing ethical issues or principles:**

As above in question 53. We would like some clarification in the ethics standards of what standard should be followed for any injury to a patient that would not be covered by ACC in non-commercially-sponsored research, such as emotional distress.

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

As above in question 53 and 54, Paragraph 18.3 outlines requirements for commercially-sponsored research, compensation for injury must be at least equivalent of ACC compensation that would be available to them for non-commercially-sponsored research. We agree with the principle. From a practical perspective we ask for further guidance on how to meet this requirement, specifically how to determine the level of compensation that is at least equivalent to ACC compensation.

Furthermore, we would like some clarification in the ethics standards of what standard should be followed for any injury to a patient that would not be covered by ACC in non-commercially-sponsored research, such as emotional distress.

The last sentence in paragraph 18.3 states the commercially-sponsored research “must include ‘no-fault’ compensation”. We do not believe the intent is for this ‘no-fault’ compensation requirement to cover all injury from commercially-sponsored research without exclusion, for example, in cases of medical negligence. In paragraph 18.7 it states that researchers must inform participants of “whether the alternative compensation is ‘no-fault’ compensation or whether fault on the part of the participants or researchers may impact on the availability and amount of the alternative compensation”. There appears to be disagreement between these two paragraphs and we request clarification on the scope of the intended principle. For reference, Medicines New Zealand Guidelines for Compensation set limitations for when compensation should be paid (refer



to section 3.4 of the Medicines New Zealand Guidelines). The guidelines are published online here:

<https://medicinesnz.co.nz/assets/Uploads/2015-Medicines-New-Zealand-Compensation-Guidelines-FINAL.pdf>

The Medicines New Zealand guidelines are referenced in Medsafe's Clinical Trial Guideline and referenced by HDEC's website.

Section 18.11 outlines that participants must be given a study card that states that the participant is not covered by ACC for injuries associated with the research and that provides an emergency contact involved in the research. We would like to seek clarity on the process for determining whether an injury is associated with the research or not and whether it is covered by ACC and what the effect this may have on patients' experience at the point of emergency care. For example, if a patient attends an emergency unit for an event that may be related to the interventional treatment, at what point will the patient, investigator and hospital be made aware that this may not be covered by ACC compensation? Could a patient potentially not receive treatment if unable to organise payment? Will an effort to determine the cause of the injury be undertaken? We believe further explanation of this principle and practical guidance is required.

Response number	72
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Research Ethics
Publish response	You may publish this submission

## Fit for purpose

Overall the content of the Standards are helpful, clear, relevant and workable  
Agree

### Please outline your reasons:

The standards follow a straightforward and systematic layout that is consistently applied across all areas so that those using the standards are able to know what is necessary, what is best practice but optional, and what criteria to apply in making decisions.

The standards are applicable to all types of health and disability research  
Agree

### Please outline your reasons:

The standards have sufficient breadth and depth to enable researchers to apply the principles in a range of contexts.

The standards balance protecting individuals with the realities of conducting research  
Agree

### Please outline your reasons:

The reality of conducting research involve ensuring that people are always engaged with in honest partnership and that any harm is minimised as much as possible and these standards enable the human rights and dignity of each participant in research to be prioritised.

The standards support researchers to navigate ethical challenges in health research  
Strongly Agree

### Please outline your reasons:

The standards provide a systematic framework that will assist researchers and others to figure out what may be ethical in a given set of contextual factors.

## Overall do the Standards?

Standards - safeguard the rights and interests of participants in research:  
Agree

**Standards - promote high-quality ethical research for social, cultural and economic wellbeing:**

Agree

**Standards - reflect the principles of the Treaty of Waitangi:**

Neutral

**Standards - foster awareness of ethical principles and practices among health care providers, researchers and the wider community:**

Agree

**Standards - help researchers think through and take responsibility for the ethical issues in their studies:**

Neutral

**Standards - help researchers give due consideration to local and national community views and perspectives:**

Agree

**Standards - protect and reassure the community:**

Neutral

### **Coverage of ethical guidance**

The standards adequately cover the ethical challenges that are present in health and disability research

Neutral

**Please describe the ethical challenges that are missing:**

The use of health data without consent, and a range of privacy issues associated with the likely new legislation will need further amendment in the near future.

### **Merging the observational and interventional guidelines**

The standards are applicable to both observational and interventional research

Agree

**Please outline your reasons:**

About time this was done. The previous documents largely duplicated each other and also gave the mistaken impression that different types of research need to use different values in considering their ethical status.

### **Scope of the standards and non-research activities**

**Is the scope of the document clear?**

Neutral

**Please outline your reasons or suggested improvements:**

'Research' needs better definition. I would recommend use of the PBRF definition "research is original, independent (which does not exclude collaboration) investigation undertaken to contribute to knowledge and understanding and, in the case of some disciplines, cultural innovation or aesthetic refinement

'Wellbeing' needs definition. I would recommend the World Health Organisation definition 'a state in which every individual realizes his or her own potential, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to her or his community.' **Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question. :**

3.9 should include the Human Rights Act and also the Universal Declaration of Human Rights and the Nuremburg Code.

### **Ethical principles**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

I am neutral as I am of the view that the only agreed values in our society are the principles of the Treaty (Partnership, Participation, and Protection) and Te Tiriti (Kawanatanga, Rangitiratanga, Manaakitanga or Oritetanga, and Wairuatanga). These are the starting point for resolving the multivalency arising from a multicultural society and a bicultural nation. Sections 2.3 and 2.4 have an unnecessarily limited acknowledgement of this starting point which is used as the basis for using the Te Ara Tika principles and the Bioethics principles. The trouble is that the Te Ara Tika principles are only one set of principles extant in Te Ao Māori and the Bioethics principles only one possible set out of many. To give an example, later in the document, the need for informed and voluntary consent is grounded in autonomy which in this section is grounded in Respect for people. I would argue that in New Zealand we are better to argue that informed and voluntary consent is necessary for partnership, kawanatanga, and rangitiratanga to be implemented, because in partnership one yes + one no = no. The reason why informed and voluntary consent is essential is not only Nuremburg but because research in New Zealand needs essentially to be grounded in partnership between researcher and participants.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

Sections 5.9 to 5.11 lose some of their strength by being at the end of the section but are an important statement. Thank you

### **Research involving Māori**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The grounding in the need to implement the Treaty | Te Tiriti needs to more explicitly underpin this section.

The section covers all relevant ethical issues and/or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

**NEAC notes the importance of all health research for Māori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?**

Agree

**Please provide feedback with reference to the paragraph(s) in question. :**

Te Ara Tika gives excellent guidelines in this regard, and this section is clearly modelled on that advice in a pragmatic fashion.

## **Research involving Pacific peoples**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

Better addressing of the sets of values that underpin Pacific methodologies like Talanga and Talanoa are needed.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

Principles such as Ofa, Malie, Mafana, and Faka'apa'apa need to be included in this section. Indeed, would that all research implemented these principles. Also, the needs for and levels of consultation need to be included, using similar models to those used in the previous section for Māori.

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

No

**Please provide feedback with reference to the paragraph(s) in question:**

## **Categories of participants**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

8.26 could commence more positively, perhaps with a statement like 'Children are human beings in their early stages of development. As such they have equality of value and dignity with all other human beings.'

### **Informed consent**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

**Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback**

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

This section should insert the modifier 'sufficient' instead of 'all' when quantifying the level of information required for participants.

9.33 is overly prescriptive and not easily implemented in a manner helpful for participants.

9.34 needs to include the legal requirements that electronic consent can clearly be identified as having been given by the person concerned.

### **Research with participants who are unable to consent**

**Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes:**

Not really. It needs to better stress the best interest test and explain more clearly what that involves.

## Deception

**NEAC seeks views on whether the guidance will meet the needs of different disciplines of research:**

I would prefer more emphasis on the need for appropriate disclosure of deception in order to assure adequate partnership, kawanatanga, and rangitiratanga.

Otherwise, what is given is adequate.

## Research benefits and harms

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

Section 10.1 needs to address the difficult issue of for whom the potential benefits of the research apply when determining equipoise and by whom they need to be provided.

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

In 10.10 under the benefits for researchers I am not sure that any of these really justify causing harm to anyone, which is the context of this table.

## Research development and design

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

11.22 and other paragraphs in this section could better discuss how students and early level researchers are monitored and supervised.

## Types of studies

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### Research conduct

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

Yes

**Please provide feedback with reference to the paragraph(s) in question:**

13.30 to 13.37 is a step in the right directions and needs a little expansion to provide clearer guidelines for methods such as netnography and to better recognise the impact of copyright issues.

### Charging participants

**Please outline your reasons:**

I rather like the high barrier. I am uninclined to make a blanket prohibition so a high barrier is the best option

### Health information

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

It covers the current areas of concern well. This section will need revision in the near future.



The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

I am not a fan of utilitarian approaches, but nor do I wish to advocate a strong Kantian approach

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Big data and new ways of using data

Neutral

**Please provide feedback:**

More protection of privacy is important. The problems with big data for me is the lack of transparency and social licence. These need better addressing

### **Databanks**

The section is fit for purpose (the content of the section is helpful, clear, relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Human tissue**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Biobanks**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Research with stem cells**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Neutral

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Neutral

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

### **Compensation for commercially sponsored intervention studies**

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable)

Agree

**Please outline your reasons why the section is or is not fit for purpose:**

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand

Agree

**Please outline any missing ethical issues or principles:**

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback

No

**Please provide feedback with reference to the paragraph(s) in question:**

Response number 73

Name	[redacted]
Organisation	[redacted]
Role	Principal Lecturer
Interest group	Academic
Publish response	You may publish this submission

Hello

Thank you for an interesting consultation day in Christchurch today.

I have tried to submit my comments via the on-line survey but alas it will not accepted my submission, so I am emailing my thoughts to you directly.

*I wonder if the scope of the document, chapter 4 , should be broader. Although I understand that the intent of this ethics document is to focus on health outcomes, research about/on the health work force does not seem to fit the broad description of research point see: 4.3*

*Although low risk, some research on/about the health workforce be could be deemed high risk. Could consideration be given to including health work force research in the box linked to point 4.3*

*Thank you for considering this request.*

Response number	74
Name	[redacted]
Organisation	The Royal New Zealand College of General Practitioners
Role	[redacted]
Interest group	Non-for-Profit / Researchers
Publish response	You may publish this submission

Dear Sir/Madam

Draft National Ethics Standards for Health and Disability Research

Thank you for giving The Royal New Zealand College of General Practitioners the opportunity to comment on the draft national ethics standards for health and disability. The College considers the standard to be comprehensive and well written, and we have suggested some minor changes in our submission.

Introduction to general practice and the College

General practice is the medical specialty that treats patients: with the widest variety of conditions; with the greatest range of severity (from minor to terminal); from the earliest presentation to the end; and with the most inseparable intertwining of the biomedical and the psychosocial. General practitioners (GPs) treat patients of all ages, from neonates to elderly, across the course of their lives.

GPs comprise almost 40 percent of New Zealand's specialist workforce and their professional body, The Royal New Zealand College of General Practitioners (the College), is the largest medical college in the country. The College provides training and ongoing professional development for GPs and rural hospital generalists, and sets standards for general practice. The College has a commitment to embed the three principles (participation, partnership and protection) of Te Tiriti o Waitangi (Treaty of Waitangi) across its work, and to achieving health equity in New Zealand.

Health equity is the absence of avoidable or remediable differences in health outcomes and access to health services among groups of people, whether those groups are defined socially, economically, demographically, or geographically (WHO). To achieve health equity, we advocate for:

- A greater focus on the social determinants of health (including labour, welfare, education, housing, and the environment).
- Funding and support to sustain the development of a GP workforce of sufficient capacity to meet population need for access to quality primary medical care, particularly in rural and high need areas.
- Sustained focus on measures to reduce smoking and to increase healthy food options for low-income families.
- Improved integration of primary, community, and secondary care health and social services which ensures the provision of high quality services.

- Universally accessible free primary health care for children and low-income families, because health inequities begin early and compound over the life course.
- A review of the funding model for primary care to ensure that resourcing is allocated equitably across diverse populations with differing needs.

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### **Submission**

#### **Scope of standard – Include a reference to complementary and alternative medicine**

The College agrees with the scope of the document and understands the difficulty of defining health and disability research. In regard to the section on “innovative practice” the College suggests including a reference to complementary and alternative medicine and the need for practitioners to be clear whether their practice is “innovative” or “unsupported.”

#### **Categories of participants – remove the word vulnerable**

The term vulnerable is problematic, as it disempowers these groups. The College advocates for a strength-based approach and one that highlights the researcher responsibilities. As such we would recommend restructuring this section to start with researchers' responsibilities, and the need to potentially offer some people more, or better, support.

We would also suggest the committee adds in a sentence stating that when research is done about these groups, it should be done in partnership with them, and steps should be taken to ensure participants and the wider community are comfortable with the research.

#### **Informed Consent**

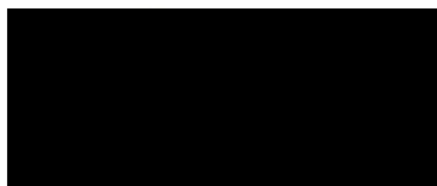
The College suggests including examples of information sheets and consent forms for different groups of participants. The College would also suggest making 9.34 into a text box or highlighting this section, as it is useful for researchers to have a reference list of everything they need to cover.

#### **Opt out consent**

The College suggests adding in an example of “opt out” consent and list some situation where it might be appropriate.

We hope you find our submission helpful. Should you require any further information or clarification please contact the College's policy team at [policy@mzccgp.org.nz](mailto:policy@mzccgp.org.nz)

Yours sincerely



General Manager – Strategic Policy



Response number	75
Name	[redacted]
<i>Department of Corrections</i>	ACC
Role	[redacted]
Interest group	Government agencie
Publish response	You may publish this submission



# ACC's feedback on the National Ethics Advisory Committee's draft National Ethics Standards for Health and Disability Research

## Fit for purpose

The Standards are clearly and usefully organised, enabling them to be operationalised as a guide for researchers and ethical oversight bodies. They incorporate a wide range of considerations on behalf of the individual, while remaining supportive and facilitative of research. The Standards apply to the range of research that ACC undertakes, commissions and funds.

## Coverage of ethical guidance

The Standards cover in good detail the ethical challenges that are present for ACC research, and non-research, projects.

## Merging of the observational and interventional guidelines

The merging is useful for ACC in that it enables us to apply the Standards to both our observational and interventional research.

## Scope of the standards and non-research activities

The Standards clearly address and define research and non-research activities. These sections are particularly helpful for ACC because our organisation undertakes many projects that use research principles, but are not definitively *research*.

## Ethical principles

The principles are clearly defined and clearly communicated with both diagrams and text. This section is relevant to different projects and people by including both Te Ara Tika and Bioethics principles. The section covers all ethical issues and principles relevant to ACC's research, and some non-research, activities.

## Data Identifiability

ACC suggests the definition of **re-identifiable data** be strengthened to *"Re-identifiable data is data from which researchers have removed identifiable information and assigned a code, but it remains possible to deliberately or accidentally re-identify a specific individual, for example, by using a code-key or linking different sets of re-identifiable data"*



Name	[redacted]
Department of Corrections	New Zealand National Committee / Australian and New Zealand College of Anaesthetists
Role	[redacted]
Interest group	Medical College
Publish response	You may publish this submission

Dear [REDACTED]

Draft National Ethical Standards for Health and Disability Research

Thank you for granting us an extension to respond to the above consultation.

The Australian and New Zealand College of Anaesthetists (ANZCA), which includes the Faculty of Pain Medicine (FPM), is responsible for the training and examination of anaesthetists and pain medicine specialists and for the standards of clinical practice in New Zealand and Australia. ANZCA's mission is to serve the community by fostering safety and high quality patient care in anaesthesia, perioperative medicine and pain medicine.

ANZCA's New Zealand National Committee has reviewed the draft standards. We found the document very long and suggest that an executive summary or other summary of the key points would be helpful.

We consider that the standards are fit for purpose and cover all relevant ethical issues. However, there needs to be a balance between adherence to good standards and producing roadblocks that hinder useful activities. ANZCA has found the ethics approval process easy to navigate to date and anticipates that this will not change.

We note the broad definition of health and disability research in the 'Scope of the standards' section and agree that clinical audit is not research. In our view, the standards need to support clinical audit processes occurring and remove any unnecessary blocks, as audit is a necessary component of quality improvement.

A statement is usually required by ethics committees that ethics review is not required for publications of conclusions and recommendations from audits. It would be helpful if the standards state that this is the requirement.

Organisations such as ANZCA conduct national clinical audits. It would be useful to clarify whether ethics approval is required for the collection of information for these national audits.

It is appropriate that the Treaty of Waitangi is a focus for the standards. An understanding of the Treaty, including the important principle of partnership, will help facilitate participation in health research and studies that may benefit Māori.

The inclusion of specific chapters in the standards on Māori and Pacific peoples is fitting because high-quality research can help to address the inequitable health outcomes these ethnic groups experience. We note that there are other causes of inequity, such as socio-economic status, rural/metropolitan differences.

ANZCA is committed to health equity. We are implementing an indigenous health strategy that includes initiatives and actions where we can have an impact. For example, through supporting an increase in the number of indigenous practitioners in the health workforce and helping them to work within the health system. We have relied on health and disability research ethnicity data to inform our work.

Consequently, we agree that researchers should collect ethnicity data unless there is a valid reason not to, such as for small studies with specific population groups. Although New Zealand may be recognised as a world leader in its ability to analyse health data by ethnicity, we believe there is still room for improvement in the collection and sharing of national data.

ANZCA agrees that different levels of consultation with Māori is required for different types of research. We suggest that further clarification could be included on what is involved in the first dot point under Research involving Māori (page 23) - Institutional ethics approval confirms the design, methods and analysis is appropriate for Māori as individuals and the collective/s. Our concern is that the process of approval needs to be efficient for researchers, while also being fit for purpose.

ANZCA and the FPM undertake research in anaesthesia and pain medicine in both Australia and New Zealand. We acknowledge the need to be mindful of New Zealand specific legislation when research is being undertaken in New Zealand. We also note the need to share the benefit of that work for Māori and Pacific peoples in Australia and New Zealand.

The section on informed consent is particularly relevant to ANZCA and FPM fellows and trainees. While ANZCA has guidelines on informed consent, these could be reviewed against the standards when they are finalised.

Thank you for the opportunity to provide feedback on the standards. We think they will be useful for our research work and for other researchers.

If you have any questions or would like to discuss this submission, please contact

Yours sincerely

[redacted]

Response number	78
Name	[redacted]
<i>Department of Corrections</i>	[redacted]
Role	[redacted]
Interest group	Government agency
Publish response	You may publish this submission

To whom it may concern

Having now scanned this large document we from the Corrections research team are very concerned about a great many elements being proposed in the document. Our submission summarises the main concerns we have.

First, and most significantly, the definition of “health and disability” research is unnecessarily broad – thus, while much of the document seems to pertain only to medical/clinical research – at time definitions stray well beyond this scope into the realms of wairua/spiritual health and general wellbeing – in others words broad enough to potentially encapsulate much of the work we do.

This is problematic and it would be my recommendation that the definition is tightened to focus on out and out heath-based research/clinical trials rather than being all encompassing of basically all social science research. For example, the current definition is “systematically collecting or analysing data to generate new knowledge; in which human beings are exposed to manipulation, intervention, observation or any other interaction with researchers either by directly changing their environment or that involves collecting, preparing or using biological material or medical or other data to generate new knowledge” (*italics added, section 4.5*).

Throughout the document the scope is contradictorily presented as narrow and broad – for example, evaluations and quality assurance processes are both included and excluded from the guidelines in a way which is unclear – basically the suggestion is that such endeavours will need to be “monitored throughout” to see whether the research guidelines should be followed – there is little specific direction for deciding when things are in and out of scope – which again leaves one to feel concerned that application could be worryingly broad.

There seems to be no distinctions within the guidelines about the size or scope of research projects: everything – no matter how small - seems to be included. This is problematic in a situation where some of our projects are small and are completed within tight time frames. There simply would not be sufficient time in most work we do to meet the ethical requirements set out in the guidelines. It is therefore my recommendation that there is some exclusion for small scale projects.

Associated to this there is also an assumption that all research will be made public and provided to participants – again the assumption seems to be based on projects undertaken external to government with external funding – the requirement to publish or ‘make public’ all research findings within a timely fashion would represent a change of current practice for the Department.

While the general ethical principles are fine – both Te Ara Tika (Tika, Manaakitanga, whakapapa and Mana) fit with our current practice, as do the bioethics principles (i.e., respect, beneficence, non-maleficence, and justice), with relation to cultural competence in relation to Māori and Pasifika, our standard approaches would benefit from further finessing to fully meet the guidelines. Marianne and I have already been working on this and are in the process of arranging cultural sessions specifically focused on researching Māori and Pasifika with Neil Campbell and Suti Ete. Certainly there are areas of our current practice which could be improved upon and we would benefit from incorporating some more ‘cultural components’ into our practice (for example, Talanoa methodology as set out in the guidelines). There are, however, other aspects mentioned in the guidelines which are outside our standard practice – these involve “early consultation” over the research design and research questions with relevant cultural communities, and being open with participants about the publication plan. There is also a requirement to compulsorily collect ethnicity data which we currently don’t do routinely, but perhaps ought to as part of our interviews. There is also requirements for cultural advisory groups around research projects which would require much additional work.

Chapter 8 is focused specifically on research with vulnerable people – this includes incarcerated populations, unemployed people and those on benefits, homeless people, sex workers, people who have been physically, psychologically, emotionally, financially, pharmacologically or spiritually abused or neglected, people with mental health issues, disabilities and literacy problems, people with substance abuse issues, people involved in illegal activities, and, somewhat oddly, women. It states that vulnerable people should not be excluded from research as this will bias the findings – this means if women are not included in projects we need to scientifically justify their absence for example. However, it also notes that based on current legal settings in NZ vulnerable people are limited in their ability to ‘consent’ to participate in research and should be avoided – in essence it suggests that the minimum number of “vulnerable people” should be included in order to answer research questions. Such guidelines are, in my view, contradictory and confusing – and it is problematic that the recommendations made in the guidelines are noted to be in contradiction of current NZ laws – where does this leave us? It goes on to say that ‘vulnerable people’ may require an impartial witness to their consent to participate in research – this requirement would create obvious problems for the majority of our research where it is not practical to have an impartial witness to consent. It also suggests that ‘vulnerable people’ should be able to access supports to assist with the consent process – again, I cannot see how this would be workable in our current research circumstances. There is also a lack of clarity about the use of koha for ‘vulnerable people’ – and whether these should be discussed in advance or simply offered ipso facto – in my view the guidelines need to be less contradictory and more tightly drafted to make it clear what is required.

There are a number of problems with the consent section. While for the most part we follow the guidelines in our standard practice – the guidelines again seem drafted for external non government research – talking about conflict of interest, institutional affiliations etc. The requirements in my view are far too arduous for “vulnerable populations” to either understand or be able to meaningfully consent to. As noted above, there are also problems with the need to have “supported consent processes” and impartial witnesses to consent. While not applicable to us currently, there are a host of consent requirements attaching to RCTs which would require a lot more than was proposed for the burglary project. In addition, the guidelines insist that consent is obtained for ‘data linking’ from participants – as we routinely do this using our administrative data this would signal a change of practice for us – while perhaps worth considering adding to our consent forms, I also worry about this and wonder whether we are in fact legally required to get

participant permission to access information that we already have in administrative files and/or linking through the IDI – perhaps something we need to discuss – although in terms of the IDI we have yet to attempt to do this as an individually-identifiable level. There are also a range of arduous clauses relating to withdrawal of information and provision of results which are practically difficult in a Corrections setting – again, my preference would be that these guidelines are not binding for our research.

While the guidelines list appropriate legislation relevant to research ethics – this is neither summarised nor specific parts of acts identified as relevant – this restricts our ability to assess the guidelines against existing legislation – recommend that this is redrafted to be more user friendly (see section 9.86).

Chapter ten focuses on the requirement for benefits and harms to be communicated to participants as part of the consent process. My sense is the guidelines are looking for much greater and direct identification of direct, indirect and general benefits and harms than our current practice. They also place considerable onus on researchers to mitigate and manage the benefits and harms, including ensuring the utilisation of research findings. This is problematic in terms of exploratory projects where application of results at the outset may not be as obvious, but also problematic insofar as researchers have little control over what happens and how influential findings are in terms of future service and policy design/delivery. The chapter also details a range of “harms” that researchers must mitigate which is very broad – including “data harm” defined as “surveillance, inferential harm or social harms such as stigmatisation” and “autonomy harm” defined as “coercion, inducement or undue influence”. The guidelines also require researchers to “scientifically or ethically justify” criteria for unequal distribution of harms or benefits – given our population, the likelihood of unequal distribution seems high and difficult to “mitigate”. There is also a requirement to manage ethical risks in an ongoing way which is not current practice – again, this may be more appropriate for larger scale projects.

In Chapter 11, the guidelines require that all research outputs are reviewed by persons with appropriate knowledge and skills who are “independent of the research”. Again, this is not common practice for us and would require new processes and have time and fiscal implications for our research if we were bound by the guidelines. The guidelines also require all projects to have a “Research Protocol” which includes a literature review setting out gaps in knowledge and justifying the need for research to be undertaken. Again, this would require an adaption to current practice. The protocol is generally far more extensive than we would currently produce and would have repercussions for project resourcing should it become a mandatory requirement. Finally, within this section the guidelines require researchers to have “adequate time and resources” to conduct research ‘safely’ (safely is not defined) and have the “capacity to disseminate and communicate research findings” publicly and to research participants. The latter requires that a “plain English” version of findings is provided to participants. Both matters would require changes to current Departmental practice.

So, in sum, should the guidelines become mandatory for us it would create significant practical problems and, as a result, significantly limit our ability to work efficiently and productively, reduce the amount of research work we could consider, and elongate time frames we would require leading into fieldwork. Our preference would be for the guidelines to be redrafted and limited to medical or clinical health research and utilised for large projects only. We may still run into problems with mental health research which sits more obviously within the “health research” domain – again, this is where the size of project may be important, with small-scale projects not meriting adherence to the full guidelines.

Response number	79
Damian Pethica	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher Government agency Academic Consumer Commercial Sponsor Other: All of these except Consumer, including sponsor but non-commercial
Publish response	You may publish this submission

Dear [redacted],

I'm sending the below (which was forwarded to [redacted] about 9 months ago) as promised to follow up on our conversation yesterday regarding the scientific assessment of proposed intervention clinical trials to assist Ethics review.

The draft NEAC Standards for Health Research e.g. sections 10.22 and 11.1 make it very clear that trials must be well designed and also represent the safest method of achieving research aims, these clauses being in line with the relevant international Guidelines.

For example, summary principles are stated in articles 3 and 4 of the current over-arching EU directive (

[https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg\\_2014\\_536/reg\\_2014\\_536\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf))

Naturally the processes regarding clinical research in NZ must at least meet such international guidelines, but our current NZ Ethics approach does differ somewhat from the more internationally usual IRB approach with clinical trials scientific assessment being done in parallel (via SCOTT) for medicines.

As discussed yesterday, no legislative change is required prior to temporary remedial action, and the proposal as attached is neither complex nor costly (but is advisory in nature, like SCOTT is currently advisory). The scientific assessment could be part of the Ethics evaluation (like an IRB) if sufficient expertise is available, or supported as is proposed in the attachment, or by some other independent source of appropriate scientific expertise relevant to devices if it exists in NZ. Independent expertise in development of medicines, including devices, is not widely available in NZ, which is probably why SCOTT was set up in the first place. Device development and regulation is fast catching up with medicines, to address their historically poor risk/benefit assessment prior to marketing. The complexity of the EU directive cited in the attachment clearly shows the challenges for regulating devices of different kinds.

As the NEAC standards will apply to health research involving devices, and NZ regulatory changes for devices are surely coming, I hope that this communication assists in relation to the draft.

I'll make other comments using the online feedback form.

Best regards

Response number	80
Name	[redacted]
Organisation	Family Planning
Role	[redacted]
Interest group	Clinical and Health Promotion Service Provider
Publish response	You may publish this submission

Tēnā koutou

Thank you for the opportunity to provide comment on the Draft National Ethical Standards for Health and Disability Research. While Family Planning staff engage in some limited research, it represents a small proportion of the work of our organisation. Therefore, we have not completed the online submission, as it requires commenting on a number of more detailed aspects of the standards, which we believe are beyond our area of expertise. Instead, we are commenting on the standards as they relate to our work and the interests of key stakeholder groups, namely groups who experience inequity in health outcomes, including Māori, women and young people. Overall, Family Planning believes the standards are robust, appropriate and will provide useful guidance to both our staff who engage in research, and our Family Planning research committee, which reviews proposals from external researchers to involve Family Planning in research projects.

## Introduction

Family Planning is New Zealand's largest provider of sexual and reproductive health services and information. We are a non-governmental organisation operating 30 clinics as well as school and community-based services. We offer accredited clinical courses and workshops for doctors, nurses, midwives and other clinicians working in sexual and reproductive health.

Our health promotion teams run professional training and education programmes in schools and the community for children and young people, parents, teachers and other professionals.

Family Planning New Zealand is committed to increasing health equity as a strategic priority.

## Defining the boundaries of health and disability research

We strongly support point 4.3 which provides a comprehensive description of research. We welcome the use of the World Health Organisation (WHO) definition of health as “a state of physical, mental, spiritual and social wellbeing rather than simply the absence of disease or

infirmity.” We also strongly support the focus on addressing disparity and contributing to whānau ora. This approach to defining research rightly acknowledges that health inequity is the key challenge facing the health sector in New Zealand, and that health equity, for Māori in particular, requires generating knowledge about the full range of factors that impact health and wellbeing.

## Research involving Māori

While the issues of consultation with Māori and sharing benefits of research with Māori are addressed expansively, it does not appear that the issue of data ownership or data sovereignty is raised in the document. As there is growing interest in indigenous peoples’ right to data, it may be worthwhile considering whether advice should be provided through the standards.

We question the wording of point 6.11 which states “All research in New Zealand is of interest to Māori: every study can offer a training opportunity for a Māori researcher;...” While we do not believe it was intentional, this wording implies that there aren’t accomplished and experienced Māori researchers engaging in research already.

Under point 6.20, Box 1 on page 23 describes the expectations for consultation with Māori, based on the extent to which the research involves Māori. It is surprising that for Māoricentred research, which involves Māori at all levels, there is no minimum standard of Māori leadership of the research? It would seem reasonable that the standards would recommend that Māori-centred research should include at least one Māori lead researcher alongside consultation with Māori.

Family Planning particularly welcomes the advice provided in point 6.27: An important step in addressing inequalities and achieving health equity is to identify inequalities by consistently collecting good-quality ethnicity data. Such data can be a source of comparative data and can influence the outcome and recommendations of research. It can also support research in its contribution to improving Māori health outcomes and reducing inequities.

Particularly in the area of sexual and reproductive health, there is little or no national data. For example, there is no national data on contraceptive prevalence. Therefore, it is not possible to explore inequity in sexual and reproductive health across ethnicities. The little data that does exist shows inequity in sexual and reproductive health outcomes. As the standards identify that addressing disparity is a key purpose of health and disability research, it is valuable that the standards also highlight the importance of obtaining data which has the power to identify inequity across populations.

Family Planning questions why the standards for research involving Māori and Pacific Peoples are not more closely aligned? For example, the standards state that research involving Māori must demonstrate cultural rigour, while research involving Pacific Peoples must demonstrate cultural integrity? While it is likely the differences are intended to reflect the rights of Māori as the indigenous people of New Zealand, it is unclear why different terms are used and what the different approaches would mean in practice.

## Categories of Participants - Participants in a situation of power imbalance

Section 8.20 describes people who may be at risk of unequal power relationships with researchers. It may be useful to include people who regularly experience discrimination in society – such as Māori, Pacific Peoples, women, LGBTQI people and people who are lowincome. People who



experience discrimination may feel greater pressure to comply with research requests to avoid any conflict or further prejudice.

#### Research in children and young people

Overall, Family Planning believes the section on children and young people is clear and useful. In particular, the evolving capacity of young people and how evolving capacity relates to young people's involvement in research is explained well.

In section 8.36, where the document provides examples of the types of research which might be sensitive, it would be helpful to use the term young people rather than children when discussing disclosing sexual activity.

#### Research in women

Family Planning believes paragraph 8.37 is problematic. It states: "Women have historically been excluded from much health-related research because of their childbearing potential. However, as women have distinctive physiologies and health needs, they must be included in research wherever possible". Family Planning believes women's health needs have historically been under-researched for two reasons: 1) most research typically involved men and results were simply extrapolated to women, regardless of their reproductive potential, without recognition that women have different physiology; and 2) because of discrimination against women in society. In the past, there were very few women in leadership roles in society, government and research institutions. Decisions about research priorities and funding allocation for research have historically been made by men. The interests and health needs of women have not been prioritised. There are still areas of women's health which are underresearched, such as reproductive and gynaecological issues. We believe it is inaccurate to indicate that women's reproductive potential is the only reason why women have been excluded from research.

It may be useful in this section to discuss the importance of women leading and contributing to research about women. Particularly where research is centred on issues where women are primarily victimised, such as sexual assault and domestic violence, researchers must be competent in their understanding of gender stereotypes and dynamics in society, as well as sensitive to the impact on women's lives and wellbeing.

In paragraph 8.38, the standards should advise researchers to ensure women participating in research about sensitive issues are provided with contact information for accessible support services if they need it.

#### Seeking Ethics Committee approval

It does not appear that the standards include advice on when to seek ethics committee approval for a research project. From Family Planning's experience, it seems that all research conducted by a researcher associated with a university or tertiary institution is likely required to have ethics committee approval. Similarly, research conducted within a DHB in a clinical setting requires ethics approval. However, for NGO organisations and researchers who operate outside of a university or DHB setting, it is sometimes unclear under what circumstances ethics committee approval should be obtained, particularly where participants are anonymous or data is de-identified. There are limited ethics committees operating independently from universities. For NGOs, trying to seek ethics approval for a small research project can be a barrier. However, it is important that NGOs can feel confident that ethical standards have been met when engaging in any type of research. The standards state that they apply whether or not ethics committee approval is required (point 4.1).

Family Planning requests that the standards provide guidance about when to seek ethics committee approval for research.

### Summary

In summary, Family Planning believes the Draft National Ethical Standards for Health and Disability Research are fit for purpose and well-informed. They are particularly useful for considering the ethical issues regarding research with Māori, Pacific people and young people. We suggest further consideration of a few issues, including recognising a broader list of people who may experience power imbalances in research due to discrimination by society. We also request guidance on when it is advisable to seek ethics committee approval for research.

Thank you for the opportunity to make a submission.

Ngā mihi nui

Response number	81
Name	[redacted]
Organisation	[redacted]
Role	Lecturer in philosophy
Interest group	Academic
Publish response	You may publish this submission

## Feedback on the Draft National Ethical Standards for Health and Disability Research

### Comments on the standards

Thank you in advance for taking the time to consider my recommendations. I want to make two: the first concerns the number of bioethical principles. I want to suggest adding another that emphasises the ethical relevance of relationships. These recommendations concern section 5 of the draft.

The relationships we stand in to others can make a radical difference to what it is ethically permissible for us to do. That is, they can alter the stringency of any existing obligations we have, and generate new ones all of their own. This acknowledged in the Te Ara Tika principles, but it is not highlighted in the corresponding bioethics principles. So I recommend adding a principle that does

My second recommendation concerns the content of the existing bioethical principles. At present their wording leaves it ambiguous whether they are to be taken as rules or guides (although in some cases the wording invites a rule interpretation). And the term 'principle' is itself ambiguous between these interpretations.

I think it is extremely important that they be construed as guides that should inform judgement, rather than as rules that replace the need for it. I think this 'guidance' notion of a principle needs to be emphasised in the preamble, and that the wording of the principles themselves needs to be changed to reflect this. (I don't think the wording explicitly contradicts a guidance interpretation, but it doesn't really invite it either – and I think the default is that people interpret principles as rules).

I will now provide a brief-ish defence of these proposals.

#### Recommendation: a fifth bioethics principle - relationships

The relationships we stand in to others, including to our communities and institutions, can radically alter what it is ethical for us to do. They can make more or less stringent existing obligations, and can generate new ones just by themselves. We all recognise this in everyday life. We recognise that we can make certain criticisms and jokes and requests to friends and partners that it would be unethical – sometimes highly unethical - for us to make to strangers, and vice versa. It is not that our friends and partners are ethically more important than strangers, or more liable to harm, or possess greater autonomy etc. So one can't plausibly cite the considerations mentioned in the other principles to explain this.

Relationships are mentioned repeatedly in the Te Ara Tika principles, but not once in the bioethical principles. As such I believe a separate principle – like the one we have in the Massey code of ethics – devoted to stressing the ethical significance of relationships should be added to accommodate this.

Principles as guides not rules.

The word 'principle' is ambiguous between a rule and a guide. Yet the difference is highly significant and so it should be made clear which interpretation the term is to be given.

In my view ethical principles should be explicitly construed as guides. The first reason for this is that if the principles are construed as rules – and in some cases their wording invites this interpretation - then they all seem to be false because in every case it is easy to imagine exceptions (and as reality outstrips our imaginations, reality can be depended on to provide even more exceptions than we can think of). By contrast, if they are guides, then they are all uncontroversially true.

The second reason is that rules replace the need for moral perception and judgement. If I have a rule, then I don't need to exercise judgement, for the rule does the work for me and all I need to do is follow it. So by offering rules one discourages the exercise of moral perception and judgment by supplanting the need for it. In my view that's a bad thing because it is ultimately our moral perception and judgement that provides us with our insight into what is ethical.

Guides rather than rules.

Ethics seems to be messy. A consideration that makes one act ethical can just as easily make a different act unethical. The ethical relevance of a feature seems to depend on its context. But ethical rules presuppose that there are some considerations or sets of considerations that always operate the same way whatever the context. And this seems false, as I will now argue, using the existing principles as examples.

Respect for autonomy.

Although the autonomy of a person is normally something that demands respect – and thus respecting it is most often an ethical positive – this is not invariably the case. For instance, I would be respecting and enhancing the autonomy of a convicted criminal if I released him/her from prison. Yet clearly that would be bad in this context. That is, the fact my act promotes this person's autonomy – and it unquestionably does - is actually part of why it is wrong. So, in this context respect for autonomy operates as a wrong-maker, not a right-maker. Similarly, there are those who, for a variety of reasons – certain kinds of insanity or irrationality – might not be able to exercise their autonomy responsibly. Respecting and enhancing such a person's autonomy may sometimes be bad, not good.

I think the fact that respect for autonomy is typically an ethical positive rather than invariably one should be emphasised, so that room for judgement is left for when and where it operates positively.

Beneficence.

As currently worded, the principle says that what counts as a benefit may vary between individuals. But what isn't also stated is that whether a benefit counts as an ethical positive or ethical negative also varies from context to context.

For example, imagine a researcher wants to carry out research on torture victims. Normally an ethics committee might be slightly worried about the well-being of the researcher due to the harrowing nature of what they might have to see and hear and will want some provision to be made to deal with this. But what if the researcher points out that he/she is a sadist and as such carrying out this valuable research will benefit him/her by satisfying his/her sadistic desires as well as promoting knowledge? It seems to me that these benefits make the research less ethical, not more. There are some things we ought not to derive benefit from - typically, we ought not to derive benefit from hearing about or witnessing the suffering of others - and thus in this context the benefit to the researcher actually counts negatively, not positively.

Benefits can also be ethical negatives when they are positively undeserved. It is bad when a criminal benefits from their crime, for instance.

So benefits are typically ethical positives, but they are not invariably so and can sometimes count as ethical negatives. I think it would be good if the principle of beneficence stressed this as it is not at the moment clear whether it is to be interpreted as a guide or a rule.

Also in this particular case the current wording includes the claim that benefit is “the basic aim of good research and its fundamental justification”. That seems contentious. What if – as seems entirely plausible - we’re all better off not knowing what’s true? That would mean good research may sometimes involve fabricating results. But that’s surely bad research even if we’re all better off for it. Personally I think it is more plausible that discovering the truth is the goal of most research. But perhaps that’s contentious too – my point is just that contentious claims about the goals of research should be removed from the content of the principles.

#### Non-maleficence

I think everything said above about beneficence applies equally to non-maleficence. Just as benefits are not always ethical positives, harms are not always ethical negatives. The same examples can be used. There are some things that ought to distress us, that ought to make us unhappy, and if we are not distressed or made unhappy by them then that is bad not good.

Also, sometimes a harm would have occurred anyway, and this can operate to make the harm ethically irrelevant (though it won’t always do so).

Harms can also be good when they are deserved. We harm criminals by incarcerating them, but in these cases the harm is plausibly good, not bad and is part of the justification for incarcerating them.

Additionally, if taken as a rule – and its wording invites it because it says “the risks of harm in research should not be greater than its expected benefits” –this principle conflicts with the principle of respect for autonomy.

What if I am well aware of the risks some research poses to me, but nevertheless wish – upon careful consideration - to participate? Stopping informed people from participating in research could– depending on the context - be extremely disrespectful of their autonomy. It can display an unethical paternalism. So sometimes – though obviously not always – it is unethical to prevent others, including communities, from making informed decisions about the risks they wish to run.

Paternalism is not always wrong, but it is often wrong, especially when dealing with those who possess a robust autonomy, and a principle that invites us to think that research must never risk harm greater than benefits fails to acknowledge this. So again, I think the wording needs to be changed so that it is made clear that harms are typically wrong-makers, rather than they always and everywhere are, and I don’t think any claim should be made about the quantities of harm versus benefit, as once more there is no simple algorithm here.

Justice.

There are two aspects to justice: fairly distributing benefits and burdens, and giving people what they deserve. Starting with equitable distributions of benefits and burdens - sometimes greater equity can be achieved by increasing burdens rather than increasing benefits. Is that going always and everywhere to be ethical? That seems unlikely. Sometimes (often) creating greater equality by increasing harms is going to be unethical, not ethical. Not always – perhaps sometimes increasing harms is ethical and is ethical precisely because it promotes justice (this would be another example of harm operating as a right-maker, rather than a wrong-maker) – but sometimes.

Relatedly, sometimes a just situation can be created by highly unethical behaviour. For instance, it is plausible (though it won't always and everywhere be true) that someone who subjects others to racist discrimination thereby deserves to be subject to some of it (this is what the *lex talionis* – the eye for an eye principle of retributive justice - would say, anyway). So imagine we have a situation in which two racists of different races are engaging in systematic racist discrimination against each other. Well, plausibly they are both getting what they deserve. But it is also clear that they are both behaving highly unethically. So the situation is a just one – both are getting what they deserve - but the behaviour that is creating it is wrong, not right. Sometimes, then, wrongful behaviour – behaviour that one ought not to engage in - can create a just situation, as in this case. Similarly, it is sometimes right to create unjust situations. If one of the two racists described above changes his/her ways and ceases to be a racist, they have done what is right, yet by doing what is right they have now made the situation into one that is unjust – for they are now being unjustly subject to racist discrimination.

If what I have said about these situations is correct, then it can sometimes be unethical to create a just situation, and ethical to create an unjust one. Obviously that will not always be the case – more often than not it is ethical to promote justice and unethical not to. The point is just that this is not invariably the case, as the above examples show.

Justice is also about ensuring people get what they deserve. But although it is typically right to give people what they deserve, it is not always and everywhere right to do so. For instance, some people have committed such wicked deeds that, plausibly, what they now deserve no decent person ought to give them. Perhaps torturers deserve to be tortured (the *lex talionis* would say so) but – strange circumstances aside – it is unethical to torture people and thus ethics prevents us from dealing justly with torturers. Sometimes, then, it can be unethical to give a person what he/she deserves. So, as with all the other principles, the consideration that justice calls attention to – the fair distribution of benefits and burdens and giving people what they deserve – is not one that is always and everywhere an ethical positive.

## Summary

I have tried above, admittedly with some rather crude examples, to illustrate a general point, namely that a feature that counts ethically positively in one context, can count ethically negatively in another, and that this seems to apply to all of the features highlighted in the principles. If that is true, then the principles need to be interpreted as guides if they are to be accurate. At present I don't think their guiding nature is clear, and I would personally recommend changing the wording of each a little so that their typical rather than invariant ethical significance is acknowledged.

Thank you very much for taking the time to consider my proposals above and apologies if I have laboured the points or been altogether too philosophical!

Response number

83

Name

[redacted]

Organisation

HQSC

Role

[redacted]

Interest group

Government

Publish response

You may publish this submission

**Part one: general feedback**

Please choose the number that best represents your response to each of the statements that follow.

**Fit for purpose**

1

Overall the content of the Standards is helpful, clear, relevant and workable.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons.

It is pleasing to see on pages 58-59 the researchers' skills and resources specified. We believe that to strengthen this at 11.21 it should read MUST instead of MAY. This is important because there are many complexities to research and protecting participants from harm and conducting relevant and well-designed research requires trained and skilled researchers.

2

The standards are applicable to all types of health and disability research.

5	4	3	2	1
Strongly disagree	Disagree	<b><u>Neutral</u></b>	Agree	Strongly agree

Please outline your reasons.

We believe there should be mention of translational research. Many definitions have been given for translational research, a useful one is that it is a systematic effort to convert basic research knowledge into practical applications to enhance human health and wellbeing. It is important for research to be useful and have the potential to address inequities and improve health outcomes. This could be included on page 12. There needs to be more mention of co-design as an approach that involved consumers in research as more than just participants in studies. A definition of consumer could be provided in the general definitions on page 9.

3

The standards balance protecting individuals with the realities of conducting research.

5	4	3	2	1
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Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree
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Please outline your reasons.

4 The standards support researchers to navigate ethical challenges in health research.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons.

The ethical comportment in research is critical to uphold and understand. One area where we believe there needs to be more clarity is around when to inform, and whose responsibility it is, participants about changes in data and new evidence and information that comes to light while studies are being undertaken. There is opportunity to modify participant information sheets which is necessary particularly when some studies have difficulty in recruitment and are extended. New information comes to light which may not be included in current participant information sheets and may influence the decision of potential and current participants. This needs closer oversight of the data monitoring committee which is described on page 73. It should be stipulated that this committee must ensure that information to participants is current.

4.a Overall do the guidelines?

	5 Strongly disagree	4 Disagree	3 Neutral	2 Agree	1 Strongly Agree
safeguard the rights and interests of participants in research				√	
promote high-quality ethical research for social, cultural and economic wellbeing				√	
reflect the principles of the Treaty of Waitangi				√	
foster awareness of ethical principles and practices among health care providers,				√	



	5 Strongly disagree	4 Disagree	3 Neutral	2 Agree	1 Strongly Agree
researchers and the wider community					
help researchers think through and take responsibility for the ethical issues in their studies				√	
help researchers give due consideration to local and national community views and perspectives				√	
protect and reassure the community.			√		

### Coverage of ethical guidance

- 5 The standards adequately cover the ethical challenges that are present in health and disability research.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please describe the ethical challenges that are missing.

Not necessarily missing, just more emphasis and clarity around informed consent in the cases of data monitoring and shifts in evidence, as described previously.

### Merging the observational and interventional guidelines

- 6 The standards are applicable to both observational and interventional research.

5	4	3	2	1
Strongly disagree	Disagree	<b><u>Neutral</u></b>	Agree	Strongly agree

Please outline your reasons.

This area could be stronger in relation to inclusion and information of participants, power imbalances

### Scope of the standards and non-research activities

In January and February 2015, the National Ethics Advisory Committee (NEAC) sought feedback on the cross-sectoral ethics arrangements for health and disability research, issues with these arrangements and ideas for enhancing them. One of the questions related to audit and related activities. A theme was the difficulty in determining what an activity was, research or not research, and subsequently the appropriate level of oversight.

The NEAC standards are written for a research audience, as well as those who support research including ethics committees and research offices. The standards are likely to be used to determine oversight of activities. The 2012 set of ethical guidelines contained some guidance on the distinction between research and non-research activities. This distinction is used to help determine ethical oversight, and in some cases whether informed consent is required (for example with audits, which routinely do not require consent). Most submitters did not think that the current classification acts as a barrier to audit and related activity. But many noted that the unclear distinction between observational research and audit could result in:

- unnecessary ethical review of audits and related activities
- weakening of research methodology to avoid HDEC review
- failure to publish important generalisable findings.

Definitions have been included in the draft standards, and some have been tightened, however how to determine what an activity is has not been included.

It is difficult to provide a clear-cut distinction for the following reasons:

- The intent or aim (and justification) of both research and non-research activities relating to health and disability is often to improve patient outcomes.
- In both kinds of activities, the patients who benefit may be different to those who are involved in the activities.
- Creating knowledge is fundamental to research but is also clearly the aim of audit. Although some might claim broadly that research aims to create generalisable knowledge:
  - some kinds of health and disability research (eg, qualitative research) do not have this aim
  - some non-research activities clearly produce generalisable knowledge. For example, the audit of a particular department might well alert others to relationships between outcomes and practice in their own location.
- Some methods used in research are often also used in non-research activities. For example, many forms of research collect and analyse patient data but so do those who are auditing a clinical department.
- Both research and non-research activities can carry risk of harm – but some research may not go beyond minimal risk.

The Standards contain more information on determining risk and benefit of activities which may assist in determining appropriate level of oversight, opposed to oversight based on classification.

7 Is the scope of the document clear?

5	4	3	2	1
Strongly disagree	Disagree	<b><u>Neutral</u></b>	Agree	Strongly agree

Please outline your reasons or suggested improvements.

8 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

☒ Yes

☐ No

Please provide feedback with reference to the paragraph(s) in question.

page 12 of the document (under 4.6 in the box, last 2 dot points):

p.12, last dot point:

Quality improvement involves cycles of **change** that are linked to measurable assessment with the goal of improving **the experience, process, safety and efficiency of health care.**

For an activity to be considered quality improvement, **it must be** conducted at a **scale within the scope of data for improvement to test changes to the systems and processes of healthcare, it must not be conducted to generate evidence to support efficacy of treatment interventions.**

1. The Health Care Data Guide: Learning from Data for Improvement

Provost LP, Murray S. The Health Care Data Guide: Learning from Data for Improvement. San Francisco: Jossey-Bass; 2011.

## Part two: feedback on sections

### Ethical principles

#### General questions

- 9 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

- 10 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline any missing ethical issues or principles.

--

- 11 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

- ☐ Yes  
☒ No

Please provide feedback with reference to the paragraph(s) in question.

--

## Research involving Māori

### General questions

- 12 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

- 13 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline any missing ethical issues or principles.

- 14 NEAC notes the importance of all health research for Maori. The Committee seek feedback on the level of guidance on consultation – does it make what is required clear, and are the levels of consultation required appropriate?

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please provide feedback with reference to the paragraph(s) in question.

## Research involving Pacific peoples

### General questions

- 15 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

- 16 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline any missing ethical issues or principles.

--

- 17 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

☐ Yes

☒ No

Please provide feedback with reference to the paragraph(s) in question.

--

## Categories of participants

### General questions

- 18 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

- 19 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline any missing ethical issues or principles.

--

- 20 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

☐ Yes

☒ No

Please provide feedback with reference to the paragraph(s) in question.

--



## Informed consent

### General questions

- 21 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

- 22 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline any missing ethical issues or principles.

--

- 23 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

- ☐ Yes  
☒ No

Please provide feedback with reference to the paragraph(s) in question.

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## Research with participants who are unable to consent

NEAC's role is to determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services. NEAC must also ensure that any advice and guidelines comply with the laws of New Zealand. This requirement

created a tension between providing ethical guidance that may be in conflict with New Zealand law. NEAC notes that the law on research with participants who are unable to consent restricts when research can be carried out in this population.

Once researchers have demonstrated that the participation of individuals who are unable to consent are necessary to answer the research question, Researchers must balance risks of harm with benefits.

Although in some cases it may be ethically justifiable to use different calculations of benefit and harm depending on the level of risk to which the participant is exposed, as well as whether the participants in the study have potential prospective benefit derived from their involvement, New Zealand law requires participation in all cases of health research without consent to be in the individual participants' best interest.

Therefore, NEAC was unable to set alternative levels of risk and benefit as that guidance / those standards would not be able to be legally met.

Given the current legal environment, does the ethical guidance provided in the draft standards provide clarity for the regulatory and ethical environment? NEAC notes that they can revisit the ethical advice if the law changes.

Please outline your reasons.

### Deception

The standards must apply to all cases of health research. In some fields of research, for example psychological research, deception may be used for scientific validity. Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective non-deceptive alternative procedures are not feasible. NEAC has not considered deception as inherently unethical, but it should only be used as a last resort, not as a first resort, and certainly not a norm in health research.

NEAC seeks views on whether the guidance will meet the needs of different disciplines of research.

Please provide feedback.

## Research benefits and harms

### General questions

- 24 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

- 25 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline any missing ethical issues or principles.

--

- 26 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

- ☐ Yes  
☒ No

Please provide feedback with reference to the paragraph(s) in question.

--

## Research development and design

### General questions

- 27 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

- 28 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline any missing ethical issues or principles.

--

- 29 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

☐ Yes

☒ No

Please provide feedback with reference to the paragraph(s) in question.

--

## Types of studies

### General questions

- 30 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

- 31 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline any missing ethical issues or principles.

--

- 32 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

☐ Yes

☒ No

Please provide feedback with reference to the paragraph(s) in question.

--

## Research conduct

### General questions

- 33 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

- 34 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline any missing ethical issues or principles.

--

- 35 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

- ☐ Yes  
☒ No

Please provide feedback with reference to the paragraph(s) in question.

--

### Charging participants

- 36 NEAC acknowledge that charging participants is an ethical dilemma that has not been addressed in earlier guidelines. The current guidance places a high barrier to charging participants. Are the

above standards a high enough barrier to very seldom allow charging for participation, and only permit it when it would facilitate important research?

Please outline your reasons.

--

## Health information

### General questions

- 37 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

- 38 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline any missing ethical issues or principles.

--

- 39 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

☐ Yes

☒ No

Please provide feedback with reference to the paragraph(s) in question.

Big data and new ways of using data

Use of data for research is becoming increasingly complex, involving linking across different agencies and use of algorithms or artificial intelligence. The ethical standards provide guidance when using data in order to increase public benefit while respecting people.

40 Do the standards present a reasonable balance between facilitating use of data while respecting rights to privacy and respect of people?

Please provide feedback.

Databanks

General questions

41 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	<u>Neutral</u>	Agree	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.



Mandatory databanks

14.63 Government agencies may establish mandatory registries and databanks (eg, the New Zealand Cancer Registry), in which participants are obliged to provide data rather than volunteering or consenting to do so. Research using such registries and databanks may be mandated (eg, one of the purposes of the New Zealand Cancer Registry is to provide a basis for cancer survival studies and research programmes), **which may not require ethical review or a waiver of consent.** However, for research studies that use data from such databanks or registries and combine it with other data (eg, collected from participants via questionnaires), researchers must obtain participants' consent or seek a waiver of consent.

From our perspective it would be good to get clear guidelines on when ethics approval is required to use these data and when it is not. Currently we are working on the advice that our analytic work falls largely into the 'audit and QA activity' category and is out of scope but the guidance leaves it open in 14.63 above. This leads to confusion from stakeholders. One option is for us to seek an exemption on every single piece of work we do, or preferably get the wording sharpened so it is clearer when we are out of scope. I know Natalie received an exemption for the staff culture survey to address criticism, it would be preferable if NEAC's document could do this.

42 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline any missing ethical issues or principles.

43 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

- ☐ Yes
- ☒ No

Please provide feedback with reference to the paragraph(s) in question.

--

## Human tissue

### General questions

44

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

45

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<b><u>Agree</u></b>	Strongly agree

Please outline any missing ethical issues or principles.

--

46

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

☐

Yes

☒

No

Please provide feedback with reference to the paragraph(s) in question.

--

## Biobanks

### General questions

- 47 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	<u>Neutral</u>	Agree	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

- 48 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	<u>Neutral</u>	Agree	Strongly agree

Please outline any missing ethical issues or principles.

--

- 49 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

☐ Yes

☒ No

Please provide feedback with reference to the paragraph(s) in question.

--

## Research with stem cells

### General questions

- 50 The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	<u>Neutral</u>	Agree	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

- 51 The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	<u>Agree</u>	Strongly agree

Please outline any missing ethical issues or principles.

--

- 52 Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

- ☐ Yes  
☒ No

Please provide feedback with reference to the paragraph(s) in question.

--

### Compensation for commercially sponsored intervention studies

#### General questions

53

The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).

5	4	3	2	1
Strongly disagree	Disagree	<u>Neutral</u>	Agree	Strongly agree

Please outline your reasons why the section is or is not fit for purpose.

--

54

The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.

5	4	3	2	1
Strongly disagree	Disagree	<u>Neutral</u>	Agree	Strongly agree

Please outline any missing ethical issues or principles.

--

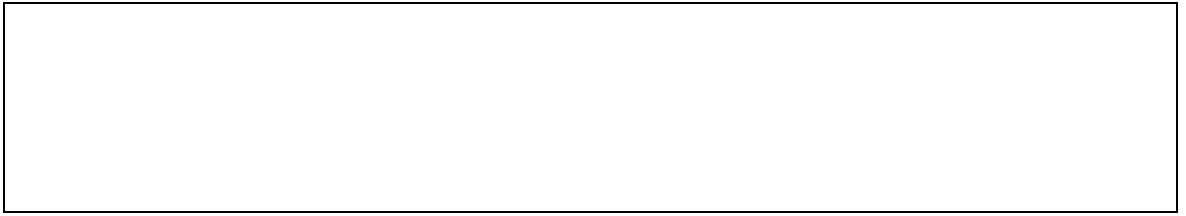
55

Do you have any comments on specific paragraphs of the section? If Yes, please provide feedback.

☐ Yes

☒ No

Please provide feedback with reference to the paragraph(s) in question.



Response number	84
Name	[redacted]
Organisation	Advisory Committee on Assisted Reproductive Technology
Role	[redacted]
Interest group	Independent ministerial advisory committee
Publish response	You may publish this submission

Tēnā koe Dr Pickering

Research on human embryos and their status under the NEAC guidelines

On behalf of the Advisory Committee on Assisted reproductive Technology (ACART) I am responding to NEAC's Draft National Ethics Standards for Health and Disability Research.

I am limiting my response to just one matter. I recommend that each of the two guidelines should state, perhaps under the heading "Scope of the Guidelines," that "all applications for research using human embryos and gametes should be submitted to the Ethics Committee on Assisted Reproductive Technology."

Ngā mihi nui,

Response number

86

Name	[redacted]
Organisation	Massey University
Role	[redacted]
Interest group	Academic
Publish response	You may publish this submission

Kia ora Nic,

Thank you for this opportunity to take part in the consultation process for the Draft National Ethical Standards for Health and Disability Research. We have circulated the document throughout our human ethics structure at Massey and the following is a synopsis of the feedback that we received:

This consultation document provides a comprehensive list of ethical standards with commentary linked to ethical principles and embedded links to other sections , and a bibliography. Emphasis is placed on researchers undertaking research that is both consistent with these standards and demonstrating this compliance to ethics committees . There are some really good sections in the standards and it has some good examples and questions , e.g. research involving Māori; a section on categories of participants; several sections on data – health, data-linking, databanks (and governance) and biobanks.

Overall, the standards and commentary:

Pull together current approaches to research ethics (therefore supporting consistency across health and disability research, and the work of ethics committees)

Address some, but not necessarily all, of the emerging ethical challenges in research Have mostly a strong 'clinical' focus, with the potential for more attention to the broad range of health and disability research that is 'non-clinical', for example social science research

Specific comments related to these standards and commentary:

1.3: An additional objective, as noted elsewhere, is that these standards would support the consistent ethical review and approval of health and disability research

4.6: The explanation of quality improvement cycles of interventions as non-research needs further clarification, specifically in relation to the exclusion of efficacy studies. 4.7: the definition of innovative practice is biomedical in nature and excludes new/innovative service models

Figure 1 could provide more portrayal of how the Te Ara Tika principles and bioethics principles are interrelated – they are currently portrayed as separate

5.8: Non-maleficence – can organisations also be included with communities?

6.7: In clinical studies, the need for the collection of ethnicity data is accepted, however the issues of inappropriate analyses related to ethnicity groupings are not mentioned as a potential harm

9.3: Suggest that “researchers must consider identifying risks of harm’ is changed to  
researchers must identify risks of harm

10.1: The requirement for social and scientific value of all research needs to be balanced by the size and intent of the study, especially those being completed for the principal aim of a qualification



(while still minimizing risks). (These standards should have relevance to all health and disability research in New Zealand, no matter the size of the study) 13.29: recruitment through research recruitment agencies could also be included 13.45: the safety monitoring plans discussed here appear to be related to clinical trials rather than other types of health and disability research

15.39: Identifying information about 'health prospects' is difficult as the area of genetic research is developing so quickly

Thank you once again for this opportunity to provide comment on these draft ethical standards.

Response number	88
Name	[redacted]
Organisation	Canterbury District Health Board
Role	[redacted]
Interest group	Researcher
Publish response	You may publish this submission

## SUBMISSION ON DRAFT NATIONAL ETHICAL STANDARDS

### Details of submitter

1.Canterbury District Health Board (CDHB).

2The submitter is responsible for promoting the reduction of adverse environmental effects on the health of people and communities and to improve, promote and protect their health pursuant to the New Zealand Public Health and Disability Act 2000 and the Health Act 1956.

### Details of submission

3.We welcome the opportunity to comment on the Draft National Ethical Standards for Health and Disability Research.

4.The CDHB is significantly involved in health research in multiple capacities, such as clinician initiated research, industry sponsored clinical trials and evaluation of health service delivery programmes instituted at a departmental level.

5.This submission has been developed with input from various CDHB employees including those with involvement in Māori health, public health, legal and innovations and managing and conducting research and has been signed off by the Executive Management Team.

6.The CDHB strongly supports the development of, and adherence to, clear ethical standards to guide research and commends the National Ethics Advisory Committee (NEAC) for producing a comprehensive document that supports this. The standards are more detailed than past versions and are helpful, clear and relevant in the context of CDHB research activities and current societal norms.

7.This submission provides suggestions as to how to make the standards even more clear and workable in an increasingly complex research environment, with a focus on improving clarity for researchers using newer research methodologies that do not fit readily into traditional categories such as observational or interventional research. The submission therefore includes perspectives from innovators and service delivery researchers.

8.Specific comments relating to particular sections are outlined below:

#### Section 1

Introduction In section 1.4, the CDHB notes that these Standards are also likely to be of interest to clinical managers and others providing institutional oversight of research projects (e.g.

'locality sign off'), within clinical communities such as hospitals or general practices.

#### Section 3

Users' Guide The CDHB notes that the definition of Sponsor (in section 3.22) is sometimes confusing, especially in investigator initiated research or research co-designed with patient groups, when the initiation, management and financing of a study may be done by multiple different parties.

The draft Standards define a sponsor as "an individual, company, institution or organisation that is responsible for initiating, managing and/or financing a study".

The role of the sponsor in Industry initiated research is usually relatively clear. The definition and role of the Sponsor in investigator initiated research is however less clear, when viewed from a researcher's operational perspective. According to the NIH (see [clinicaltrials.gov](http://clinicaltrials.gov)), sponsors include: lead principal investigators who are responsible for conducting and coordinating the overall clinical investigation. For multi-site studies, trial data should be submitted only once. (i.e. trial data should not be submitted from every study location).

The CDHB understands there is a preference for having only one Sponsor per study. We hope that future Standards introduce some clarity around who the Sponsor is, when the study 'manager' and study financier are discordant. Might it be appropriate to consider the collaborative nature of research and have Lead principal investigators and hosting / funding organisations in a co-sponsorship role?

## Section 4

Scope The CDHB suggests several small changes to the wording in section 4.3:

We suggest that the wording in the second paragraph be changed to read "...that people's health is part of influenced by a much wider range of social factors than their health care."

To avoid any confusion, we also suggest that the reference to human beings (in the plural) in the third paragraph be altered to reflect the fact that research can be carried out on a case study of 1 person, especially if a novel intervention or technology is applied to a human participant in a voluntary way, together with (written) informed consent.

The CDHB suggests that it would be beneficial to provide more clarity in section 4.20 to further define what is meant by minor innovations.

In addition further clarity would be helpful in section 4.22 on

'what to do' if the commercial sensitivity triumphs over the ethical imperative. Is there a bare minimum of what should be recorded and where?

## Section 6

### Research involving

Maori The CDHB commends the inclusion of Māori-specific content in this section, including the clear guidance regarding levels of consultation. The CDHB believes that this section covers issues relating to Māori research well and that there is nothing missing.

One small point relating to order of content was noted. Page 20, para 6.7 – the point re ethnicity data collection would sit better on page 24 under 'Ethnicity data collection.'

## Section 8

### Categories of

Participants The CDHB recommends that there should be specific mention in this section of the Standards of the potential conflict associated with recruiting family members or friends of researchers, into a study.

## Section 9

Informed Consent In relation to section 9.24 (Participants have the right to withdraw at any point in the study without retribution), the CDHB notes that while this statement is correct, within the

context of an RCT greater clarity would be useful around the difference between ‘full withdrawal’ from a study and withdrawal from study intervention, but volunteering to remain in the study, for follow-up on an intention-to-treat basis.

## Section 13

### Research Conduct

In relation to section 13.29 (Social media), the CDHB notes that one of the novel aspects of recruitment through social media is the potential for an online (digital) identity and real world identity to be dis-congruent (either through a mistake or through malicious intent by a third party: ‘identity theft’). This point should be noted in 13.29, and an additional point added to identify that the researcher has a responsibility to do their utmost to ensure that the online identity and real world identity of potential participants, is congruent.

## Section 14

### Health Data

In relation to section 14.62 (Databank governance), the CDHB agrees that robust governance structures are key to the appropriate use of health data for research purposes, especially if researchers are planning to use data without patient consent.

Health data that has been collected without consideration of its use within a databank, might nevertheless be reconstructed at a later date in a way that allows it to become part of a newly minted databank. There may however be natural custodians of the original data (for example data collected within the DHB environment, might be considered to be under the custodianship of the DHB). These custodians might be able to direct the researcher to appropriate governance structures, or even provide an appropriate governance structure themselves.

(In the example above, a DHB research governance committee might provide the most appropriate oversight).

The minting of a new databank might in turn require the post hoc development of a governance processes specific to the newly minted databank.

In summary, if a researcher is considering reconstructing preexisting data into a format that suggests it will become a new databank, then the CDHB suggests that the researcher identify custodians of the original data and seek advice about governance issues, from these custodians.

In addition the CDHB notes that footnote 34 (on page 88) mentions that health databanks have organised systems for collecting, organising and storing health information. A key feature of a databank used within the research setting is its ability to allow retrieval of information (otherwise it might be considered to be a data archive). This might be mentioned in the relevant footnote.

## Section 18

### Commercial research versus non-commercial research – role of social entrepreneurship

The draft Standards suggest that research might be categorised into commercial (such as pharmaceutically sponsored clinical trials), or non-commercial research. This distinction is important partly because it dictates how participants might be best protected in the case of study-related misadventure (ACC or appropriate indemnity arrangements).

Some research studies such as clinical validation of investigator-developed innovations, may be undertaken for reasons which, at least at the time the research is undertaken, are non-commercial. Many of these projects could be classified as social entrepreneurship, in that there is no plan to

turn the innovation into a profitable business, yet the innovation is being developed using business principles, to ensure that the innovation (device, process, service improvement or a combination of all three), can be brought to fruition in a way that allows it to be accessible to patients. Successful completion of these projects may require use of third party vendors and other 'commercial' arrangements.

To encourage the development of quality social entrepreneurship health innovations and related clinical validation activities, it would be useful to ensure that: i) social entrepreneurship clinical validation studies can be considered by HDEC using the standard scope of review documentation and beyond, as required, and that in turn ii) these trials are recognised as being non-commercial in nature. Future NEAC standards might want to reference social entrepreneurship as a sub-class of clinical trial / clinical validation activities.

9. Two areas have been identified by the CDHB for potential inclusion in the standards:

- Post disaster research - clarity would be useful as to whether it is ethically acceptable to immediately collect data post disaster with no consent where the research would be for improving knowledge for the benefit of the population here and overseas but not specifically for that patient. This same principles would also apply to collecting research data during a pandemic. e.g. during another 'swine flu'.

- Patients with 'rare and orphan' diseases that present themselves to hospitals – in the case where there is no premeditated research question, and no ethics approval in place, clarity as to whether samples can be taken for research purposes with consent would be useful. In particular, a simple process should be described to allow data to be readily captured with patient consent.

10. The CDHB have been very appreciative to date of the prompt and helpful support from the HDEC secretariat on questions of the need for HDEC review and we support the continuation of this useful service.

11. While the guidelines are clearly relevant to all research and related activities, an important and much-used component of the current guidance is the content that guides researchers as to whether an activity will require review by an Health and Disability Ethics Committee (HDEC) (as currently seen on the HDEC website). The process for seeking written confirmation that an activity is out of scope (HDEC scope of review form) is similarly important and useful, for example for public health programme evaluation, which is commonly low-risk. The written confirmation that an activity/study is out of scope is important for researchers and wider stakeholders both for the conduct of the activity but also if publication in a peer-reviewed journal is sought. These processes, including support from the HDEC secretariat, streamline our work and support the level of review being proportionate to the level of risk posed by an activity.

Response number

89

Name

[redacted]

Organisation

Statistics Nz

Role

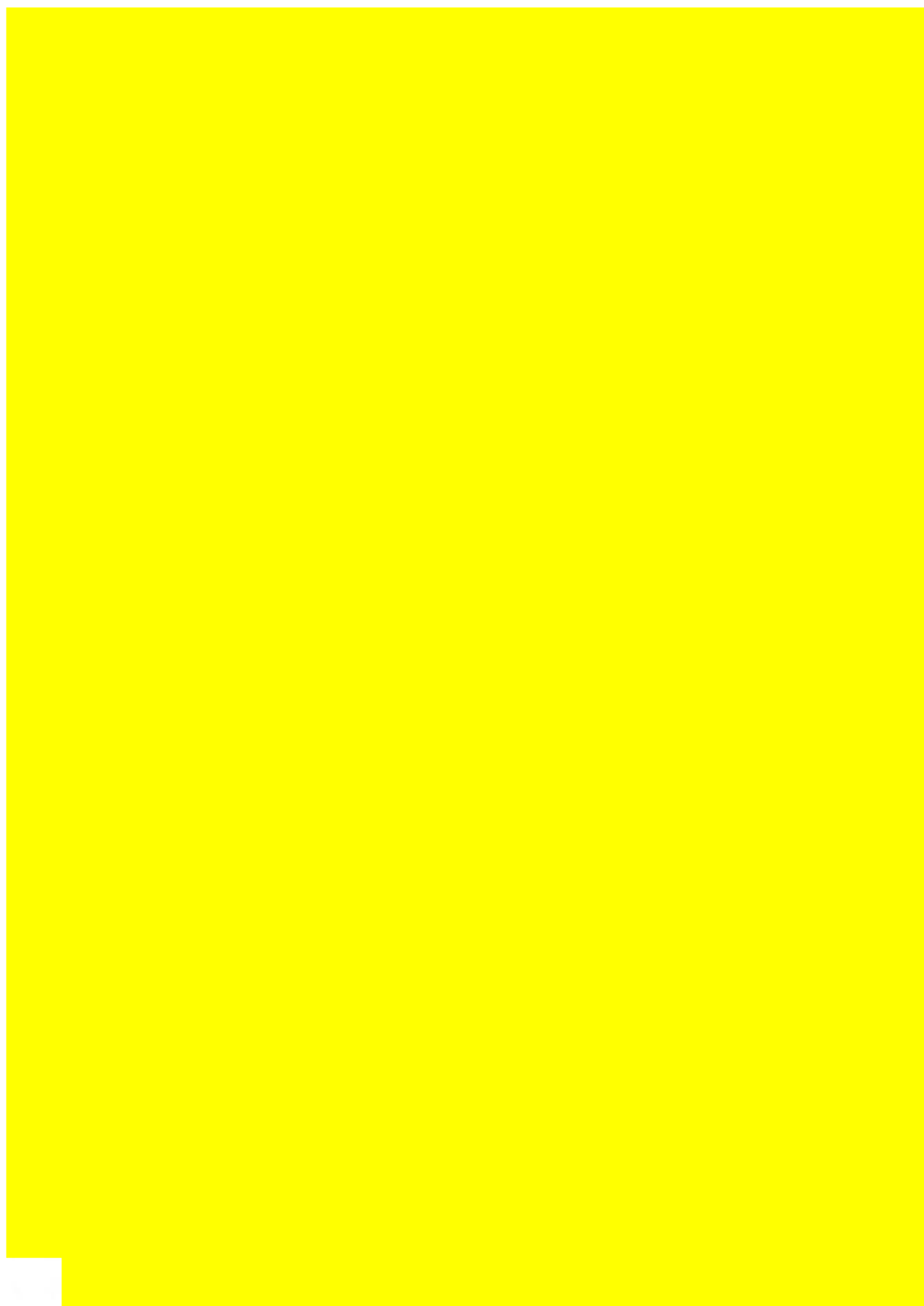
[redacted]

Interest group

Government Agency

Publish response

You may publish this submission







Response number	90
Name	[redacted]
Organisation	NZMA
Role	[redacted]
Interest group	Professional Association
Publish response	You may publish this submission

19 September 2018

NEAC Secretariat  
Ministry of Health  
PO Box 5013  
Wellington 6011

By email: [neac@moh.govt.nz](mailto:neac@moh.govt.nz)

Draft National Ethical Standards for Health and Disability Research

Dear Sir/Madam

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above consultation. The NZMA is New Zealand’s largest medical organisation, with more than 5,000 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders. Our submission has been informed by feedback from our Advisory Councils and Board.

1. We welcome the work done to develop an updated draft National Ethical Standards for Health and Disability Research. However, we have a number of high level concerns relating to both the structure and content of this important resource. A major concern is the document’s inordinate length and convoluted structure that we believe make it difficult to be fit for purpose for busy researchers. There is also a failure to adequately acknowledge competing ethical principles (with autonomy given extreme ascendancy over beneficence), overly onerous blanket requirements for researchers, and concerns about the impacts of informed consent requirements on important types of research. We have concerns that these issues could act as a disincentive to important public interest research, for little or no corresponding gain. We elaborate on our concerns in the following paragraphs and provide some suggested amendments for consideration.

Philosophical underpinnings and competing ethical principles

2. The overall philosophical approach underpinning the document tends to be legalistic (deontological) rather than consequentialist and pragmatic. The approach taken is very rigid and, in our view, does not adequately acknowledge the need to balance competing ethical principles. For example, the principle of autonomy, though clearly important, is given extreme ascendancy over beneficence. As a result, the requirements and burdens placed on researchers seem at times to be disproportionate to the actual risk of harm the rules are presumably intended to mitigate against. An example is the requirement for informed consent as a default for retrospective observational research that uses routinely collected data, where both the probability and consequences of privacy breaches are actually very small. The possible unintended consequence of this approach could be to stifle valuable public interest research for little or no corresponding gain.

#### Style and structure of the document

3. From the point of view of busy researchers, the document is unduly long, repetitious and poorly structured. We contend that a more user-friendly structure would be to have sections divided according to the fundamental type of research. With respect to ethical concerns and requirements placed on researchers, there is a fundamental distinction between interventional and observational research, yet these very different types of research are conflated and discussed together in many places in the document. We suggest that the document be restructured to include dedicated sections for these two types of research. Furthermore, with respect to observational research, it would be helpful to have additional subsections for studies according to whether the data they use are 'identifiable', 're-identifiable' and 'non-identifiable' as once again, the ethical requirements for each of these different types of research ought to be quite different.

#### Clarity for researchers about process

4. To be a fit for purpose resource for busy researchers, there needs to be easily locatable and clear advice about the need and process for ethics committee approval for interventional and observational studies. Currently, this information is difficult to find and access. For example, guidance about waivers on consent for observational studies is buried in a long list as point 14.21 on page 82 of the document. Yet the question of when waivers are needed for observational studies is likely to be one of the most common questions for researchers using the document. We suggest the use of high level flow charts or algorithms as a way to potentially reduce a lot of text and help researchers find the key information they need quickly and efficiently.

#### Unintended consequences of unduly onerous blanket requirements

5. We are concerned that the long lists of repetitive and exacting requirements for researchers that are being proposed may not always serve their intended purposes, and, in some cases, could lead to unintended negative consequences. For example, the sheer weight of compliance with these requirements could act as a disincentive to valuable research, particularly by smaller research entities that lack the administrative capacity to meet these requirements. In other cases, the requirements could simply lead to a time-wasting bureaucratic process that leads to little, if any, benefits.

#### Research involving Māori

6. We believe that this section must begin with mention of the Treaty of Waitangi. It should also include the three principles of partnership, participation and protection that are inherent in the Treaty, with notation as to what each of these principles entail. Partnership encourages and requires Māori to be involved at all levels of planning, decision-making and engaging with the Māori community. Participation enables Māori to participate across the health sector, while

protection relates to the duty of health services to recognise and response to Māori cultural beliefs, values and practices of Tikanga.

7. It is important that the Treaty of Waitangi and its principles inform health and disability research in New Zealand. Beyond the obligation to consult with Māori there are also compelling grounds for researchers to consult with Māori given the major health inequities they experience. While we are strongly supportive of meaningful partnership with Māori when it comes to research, there are some concerns that taking a blanket approach to consultation, regardless of research relevance or risk to Māori, risks undermining and discrediting situations where meaningful consultation is vitally important.

8. The process of consultation therefore should ultimately be viewed as a means to an end rather than an end in itself. While the principle of consultation, and the value of consultation for major interventional studies, are not in doubt, consultation in the 'real world' has many potential limitations that should be borne in mind. Other competing ethical principles also need to be considered. Legitimate questions include: How meaningful is the consultation process? Who is appointed to represent Māori views at a DHB level and what accountability mechanisms are these individuals and their advice subject to? What is the desired outcome of the consultation process? To what extent does the requirement for consultation improve outcomes for Māori? To what extent do the consultation requirements impede, delay or deter legitimate observational research for little gain?

9. We suggest that the objectives for consultation with Māori need to be more clearly stated. These should include the explicit goals of the consultation process and the risks the consultation process is aimed at addressing. A reasonable goal could include ensuring that any research in New Zealand should preferably improve, but as a minimum not exacerbate, existing inequities for Māori, either in the process of conducting the research or in its outcomes. In other words, the research process and outcomes must reasonably be expected to be either beneficial to Māori (preferable) or neutral. We are concerned that section 6 of the document comes close to going beyond this, to the point where the processes it mandates provide substantial opportunities for the research agenda itself to be heavily shaped and influenced (with some potential for the censoring of legitimate research proposals or questions). Some of the statements in this section, particularly point 6.11, border closely on suggesting that research proposals must all consider some kind of tangible benefits for Māori. We contend that this would be taking things a step too far and seek greater clarity on this point. The statement in point 6.11 that 'every study can offer a training opportunity for a Māori researcher' may create unreasonable burdens on small and poorly funded research groups, most of which have no funding for any researcher, let alone a Māori one. We suggest the addition of 'if possible' at the end of this sentence to convey that this is an aspirational statement.

10. As section 6 of the document is currently written, vastly different types of research are lumped together without any real sense of proportionality with regard to the degree of risk they pose to Māori and therefore the corresponding obligations placed on researchers. We would be concerned if the unintended consequences of this blanket requirement were to deter smaller less well-resourced research groups from pursuing their research, or to encourage bureaucratic less-than-meaningful consultation for research that is vitally important for Māori.

## Informed consent

11. A foremost question most researchers have is whether or not their study requires informed consent. In point 9.61, we note the document states the following: The default position is that the use of health information or tissue requires consent at the individual level. However, a waiver is legally available for use of health information and human tissue in New Zealand; researchers must

clearly justify why they need to apply that waiver, outline it in the study protocol and gain approval for it from an ethics committee.

12.Observational, epidemiologic research using data originally collected for another purpose is one of the most common forms of research conducted in clinical settings, but such research becomes essentially unfeasible if informed consent is required. The importance of this kind of research for health and healthcare in New Zealand should not be underestimated. The findings play an important role in generating and refining hypotheses, informing management and preventative policies, and shaping the broader research agenda. What researchers need is greater clarity about under what circumstances the waiving of informed consent for the use of data originally collected for other purposes is justified. We would like to see the document include an explanation of the principles governing ethical decision making with regard to the waiving of informed consent.

13.We presume that the main risk to be mitigated here is the use of private health data by third parties in ways that the study subjects would consider to be harmful. We submit that what is needed is a more consequentialist ethical view rather than simply an absolute rights-based view. If the risk of harm is vanishingly small, both in terms of its probability and impact, then this needs to be weighed against the public interest nature of the proposed research.

#### Cluster randomised trials

14.The requirement for individual informed consent to be obtained for cluster randomised trials essentially renders this type of research unfeasible. This type of trial is the 'gold standard' design for investigating preventative policy / practice / behavioural interventions in healthcare settings. They involve interventions being applied collectively to randomised units or services rather than individual patients. Any patient admitted to a unit participating in a cluster randomised trial will, by default, be 'exposed' to the intervention. Therefore, the logistics of managing patients that are unable or unwilling to provide informed consent in participating research units essentially make these trials impossible. We understand this problem is related to legislation in New Zealand rather than the position of NEAC per se. Nevertheless, we wish to highlight that this is a major impediment to quality research in New Zealand. We also seek NEAC's opinion on whether there is any room for an alternative interpretation of current legislation on this point.

15.Cluster randomised trials typically involve randomisation of units or services to interventions for which there is equipoise and very little conceivable risk of harm. Typically, the interventions being compared would be considered well within the range of completely acceptable practice / policy, and there are no a priori reasons for believing one intervention necessarily poses significantly more risk than the other. For example, in the area of infection control and prevention, cluster randomised trials might compare 'standard practice' with regard to hand hygiene education with a combination of poster campaigns / focus groups, or involve a comparison in an ICU of daily patient washes with soap and water versus chlorhexidine wipes. Another example might be randomising to different cleaning practices. In these examples, each intervention is considered within the range of acceptable, normal, safe practice and there are no a priori reasons for believing one intervention necessarily poses significantly more risk than the other.

16.Notably, outside of a research setting, if a unit / service were to simply decide to change their policy / practice, then this would be considered an entirely acceptable decision. Moreover, if down the track, routinely collected outcome data at the unit level were to be analysed as a retrospective 'quasi-experimental' or 'before-after' study, then this too would presumably be considered entirely acceptable and wouldn't require the researchers to obtain individual informed consent from everyone admitted to the unit over the study period. It appears anomalous, therefore, that randomising units to the same change in practice is somehow viewed as being an absolute

requirement for informed consent, regardless of the nature of the interventions under examination and the accompanying risk of harm.

17. The requirement for individual informed consent for cluster randomised trials represents a major barrier for generating quality research on preventative healthcare policy / practice. We believe that it is in the public interest, therefore, for NEAC to make more pragmatic recommendations to the government about waiving the need for individual informed consent for cluster randomised trials—providing certain conditions are met. These recommendations could be informed by approaches in other jurisdictions. We contend that it would be reasonable to waive the need for individual informed consent for cluster randomised trials provided the following conditions are met: i) there is equipoise between the two interventions such that changing from one practice / policy to another would be considered entirely acceptable outside of the research setting, and ii) there are no strong a priori reasons for believing that one intervention carries a greater risk of harm than the other.

#### Innovative practice

18. We note that in the section on innovative practice, the document rightly states:

4.15 Innovative practice must not be prematurely adopted into standard of care. Appropriate evaluative mechanisms should be put in place to assess the effectiveness of any innovative practice, which may include formal research, AND 4.16 Where innovative practice in health care requires research, it is an obligation of those practicing innovatively to ensure this happens at the appropriate time and in the appropriate way. The problem is that the constraints imposed by this document essentially prevent the use of ‘appropriate evaluative mechanisms’ and thus run the risk of impeding valuable innovation in healthcare delivery. This in itself should be a prime ethical consideration (currently given no place in the framing of this document).

#### Reframing the document

19. We believe that it is important to reframe, and somewhat rebalance, the document to recognise the vital importance and value of health and disability research to inform clinical management and public health policy. We suggest the addition of an up-front statement in the introduction section of the document stating this. It needs to be acknowledged that if this document doesn’t strike the right balance between competing ethical principles, then an unintended adverse consequence could be to stifle and obstruct valuable public interest research for relatively little gain. We support the principle of autonomy being at the centre of considerations but not to a point where the principle of beneficence is over-ridden and effectively forgotten.

We hope that our feedback is helpful and look forward to learning the outcome of this consultation.

Response number	91
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researchers
Publish response	You may publish this submission (anonymously)

## General Feedback

We commend the Working Party on the development of these new draft *Standards*. We acknowledge the decision to combine the two previous documents and align the *Standards* with the Health Research Strategy, although we are concerned about the length of the combined document, and whether it is clear and fit-for-purpose, particularly for those new to health and disability research and evaluation. We believe the draft *Standards* provide sound high-level guidelines for researchers to navigate ethical challenges in health research; however, we do have concerns about the translation of the high-level guidelines into practical advice for researchers and those governing research, and have provided suggestions for how we think the current draft *Standards* could be strengthened to achieve this.

Our responses to the consultation questions follow below. We have deliberately elected to not use the

Likert scale provided when making our responses, as we do not feel the scale accurately captures our views (e.g. the words neutral or agree/disagree do not capture the sentiment 'reasonable', or a starting point, but could be strengthened).

We endorse many of the points made in the submission by the New Zealand Medical Association, and would like their feedback to be considered alongside ours.<sup>1</sup>

## **Responses to consultation questions**

### **Part one: general feedback**

#### **Fit for purpose**

##### **1. Overall the content of the Standards are helpful, clear, relevant and workable.**

The Standards provide a number of helpful considerations to support research and other related activities being carried out in an ethical manner. We support the distinction between 'must' and 'should' as raised in point 3.21. However, overall the document is very long, and how the

<sup>1</sup> See: NZMA (2018): [https://www.nzma.org.nz/\\_data/assets/pdf\\_file/0003/85143/NZMA-Submission-on-NEAC-draft-national-ethical-standards-for-health-and-disability-research.pdf](https://www.nzma.org.nz/_data/assets/pdf_file/0003/85143/NZMA-Submission-on-NEAC-draft-national-ethical-standards-for-health-and-disability-research.pdf)

Standards may align with the practical implications of the ethics application process is often not very clear, at least to a new researcher. The Standards switch between principles and practical advice but there is minimal formatting in the document (such as use of boxes, diagrams, change in font size, flow charts), so it is not instinctively clear what each sub-section is about. Moreover, the distinction between 'must' and 'should' is not clear in the remainder of the document. We therefore do not think the Standards as currently drafted are fit-for-purpose. Following are more detailed reflections which we believe would strengthen the document.

From a new researcher's perspective, we believe this document would be seen as overwhelming and impractical. We strongly recommend a checklist, flow diagram, or a 'minimum expectations' section that is well-laid out and easy-to-follow for researchers to clearly see what they need to understand and do before starting on a research project. At the very least, we suggest formatting changes to emphasise standards over commentary, and to emphasise the 'must' points.

The content is overlapping, and many issues/topics are discussed in multiple chapters. Currently, it is not always clear that the issue is discussed again in another chapter. We suggest generous use of hyperlinks to ensure researchers can follow the topic throughout the document.

We suggest a glossary of key terms; this should be at the end of the document and should be an expansion of the terms defined at the end of chapter 3.

The Standards do not define their relationship with the Ethics Committees around the country. It is unclear how these Standards apply to the Ethics Committee process, and what the relationship between these Standards and the guidelines and standards for Ethics Committees is. From a new researcher's perspective, there is very little mention of the fact that ethics approval from an Ethics Committee is a related but entirely separate process to reading and following these Standards. It would be helpful to align this document to the Ethics Committee process, including links to the documentation researchers are required to fill in. We strongly urge greater alignment with the ethics application process and forms, so that 'doing the right thing is the easy thing for researchers to do'.

The only comment made with reference to Ethics Committees is that these Standards have precedence over any other standards (point 3.7). However, we are unsure how this works if a local group has a higher standard than these Standards, for example in relation to processes for Māori.<sup>2</sup> Equally, is there an expectation that these Standards are the minimum for all ethics and review groups, as is the case for researchers (point 4.1)? If so, we think this should be explicitly stated.

We suggest the Working Party re-explores each section with the lens of a new researcher and asks if it is clear what the new researcher needs to do. Moreover, we highly recommend that these Standards are tested out with new researchers to explore if they are helpful, clear, easy-to-follow, and workable.

## **2. The standards are applicable to all types of health and disability research.**

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<sup>2</sup> Double vowels are used instead of macrons in Te Reo Māori words in this document, as this convention is used by CM Health in respect of Tainui, who are Mana Whenua for our rohe.

We have made comments under question 7 for this point.

### **3. The standards balance protecting individuals with the realities of conducting research.**

Overall, the informed consent chapter, the research benefits and harms chapter, and the research conduct chapter we think are all very good and we broadly support the Standards set out in those chapters. We have some specific comments, which we have made in the respective sections of this submission (questions 21-26, 33-35).

### **4. The standards support researchers to navigate ethical challenges in health research.**

The chapter on ethical principles is very useful in considering the ethical challenges involved in health research. We suggest further commentary on potential conflicts between various principles and providing further guidance to researchers on how to navigate such conflicts. See our responses to questions 9-11.

## **Coverage of ethical guidance**

### **5. The standards adequately cover the ethical challenges that are present in health and disability research.**

We have made specific comments on these issues under the appropriate questions:

- Combination of the two separate documents into one
- Health data chapter
- Research without consent
- Types of studies
- Maaori data governance

## **Merging the observational and interventional guidelines**

### **6. The standards are applicable to both observational and interventional research.**

Overall, many ethical principles are applicable to both observational and interventional research as well as other related work such as evaluation. Issues around informed consent, research benefits and harms, and research conduct apply to both types of research, and should be upheld at all times. As such, we understand the potential value in merging the 2012 guidelines into one document. However, we have concerns that this merger has the potential to cause confusion on how to apply the Standards for the different types of studies. We also believe that the chapter on types of studies does not adequately cover ethical issues around observational research and epidemiological/public health research.

We have made additional comments on this matter under questions 30-31.



## Scope of the standards and non-research activities

### 7. Is the scope of the document clear?

We recognise the challenges in defining research, and commend the attempt in the discussion of research and non-research activities. We recognise that many people working in a setting like a DHB struggle to define whether activities fit under research or not, and so support a robust discussion around the challenges around defining research. One way is to consider all activities along a continuum, where interventional studies are at one end and audit and quality assurance activities are at the other end; this would highlight the grey area in the middle where researchers, auditors, and evaluators need to be particularly mindful of the ethical challenges present. Regardless, we strongly suggest that all activities should have consideration of ethical principles. Indeed, Point 4.5 is a stronger statement than point 4.1 and it should be said at the outset of this document so readers are aware that ethical principles apply across a range of work in the health and disability sector.

We believe that it would be helpful to define what processes to follow when there is doubt about applying for an ethics review or a waiver. In activities that do not require a formal ethics application or waiver, e.g. audit and quality assurance activities, it is important to emphasise that the ethical standards should still be upheld.

‘Public health investigations’ are classified under non-research activities (first bullet point in box under point 4.6). The examples given relate to outbreaks of disease and control of communicable conditions, and we support this statement in relation to those examples. However, we would add that there are a range of other public/population health activities that would fit under this category. We strongly recommend adding other activities undertaken by DHBs, as directed under the New Zealand Public Health and Disability Act, as part of public health investigations with relevant examples. This includes situations where the use of identifiable data is required by DHBs, in particular to support delivery of health services or quality improvement activities. Other examples include: the development of live NHI linked data as clinically actionable alerts to responsible clinicians, and regularly investigating, assessing, and monitoring the health status of our resident populations.<sup>3</sup> While a DHB undertaking this spectrum of activities should include robust methods and meet the ethical standards, generating new knowledge in this setting would not be considered as research (i.e. formal ethical applications are not required).

Specific comments:

All work undertaken in the health and disability sector should be based on robust methods, and ethically conducted. For point 4.1, we believe that these standards should apply to a broader group of people and settings, and should include auditors, clinicians, and quality improvement advisors. People undertaking all varieties of research, audit, and evaluation should meet or exceed these Standards when undertaking work in the health and disability sector in New Zealand; this should occur irrespective of whether or not a formal review by an ethics committee is required.

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<sup>3</sup> See: Ministry of Health: <https://www.health.govt.nz/new-zealand-health-system/overview-health-system/statutoryframework>

Under point 4.6, one has to be cautious with universally calling programme evaluation non-research activities, “where the sole purpose of the exercise is to refine and improve the programme or monitoring”. There is an implicit but risky assumption that the interventions are already proven within the programme. It would be helpful to acknowledge that many programmes are not always designed based on robust evidence originally and there are often significant uncertainties with regards to benefit and harms related to the active components (specific interventions) within a programme. In some cases, programmes and subsequent programme evaluations should be considered as research. There are many programmes that could be considered as experimental that are currently bypassing the ethics application process and may not be meeting ethical standards.

In a DHB setting, there is a wide range of staff that may be involved in audit and quality assurance activities, who may require access to confidential/identifiable patient information. Would this access be ethically appropriate if there is simply an audit protocol to justify this? Additionally, auditing may have secondary uses as well and this overlaps with health service utilisation reviews.

It is unclear what the Standards are in the ‘innovative practice’ section of chapter 4; this needs to be made clearer. It would also be helpful to define the role of ethics committees in the area of innovative practice.

This is an area where having clearly defined standards can be helpful, so that they can be applied more consistently across the country. Furthermore, the issue of ‘scope creep’ is often very passive and incremental change is often not obvious to the relevant authorities, and inadvertent harms related to innovative practice are often not actively considered and measured. Some of these challenges are worth acknowledging.

Point 4.11 about ‘untested or unproven clinical intervention’ is a grey area in reality. For example, let’s assume there is a hip joint replacement that is currently being used. If a company makes some improvements to the hip joint replacement with claims of potential benefits that are not proven (and the old implant model is no longer available), is the use of this improved hip joint replacement innovative practice or is this research? Similarly, what about a proven intervention that is now applied to a different cohort of people? These issues of scope creep are also present in point 4.15.

Point 4.14, we would like to know who decides what is appropriate? Are these guidelines, expert opinion, or an individual clinician’s opinion?

Point 4.19, on considerations. Under bullet point one, we suggest there needs to be a definition of what constitutes minor variation. Additionally, under point 4.19, the outcomes of many community programmes would be unknown (bullet point two). Does this mean that this is research or just that it needs to be evaluated and audited? We suggest reviewing this point again and considering if many of these considerations would be under evaluation rather than research.

We suggest the Working Party consider the boundary for research around individual and aggregated data, and the use of live and encrypted NHIs. This is particularly important for public health work and research, and is relevant to the chapter on health data. We also suggest discussion around the role of DHBs and PHOs, whether work undertaken as part of the standard

operations of a DHB should be exempted from ethics reviews. Such discussion about what are in reality difficult issues will help highlight the importance of ethical principles.

Lastly, we urge the Working Party to consider this section from the perspective of a new researcher or student, and how to best encourage them to reflect on the challenges and ethical issues present.

## 8. Do you have any comments on specific paragraphs of the section?

The definitions of health inequalities and health inequities provided in point 2.8 of the draft Standards are inconsistent with current literature. The World Health Organization (WHO) defines equity as “the absence of avoidable, unfair, or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically or by other means of stratification”. “Health equity” or “equity in health” implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential.”<sup>4</sup> We strongly recommend that the definitions of health inequalities and health inequities used in point 2.8 are updated to reflect the WHO definition of equity and equality.

We believe that the definition of health inequalities used in point 2.8 of the Standards includes concepts that are more accurately defined as health inequities. For example, “differences in the way health determinants are distributed between population groups” is considered as describing inequities because this distribution is **unfair and avoidable**. Inequalities are seen as differences that are not unfair or avoidable, for example the differences in rates of breast cancer between men and women.<sup>5</sup> While previously these terms have been used interchangeably, current best practice is to make a clear distinction between the two terms, and to make a case for improving health equity.

We believe that point 2.8 should define both terms to prevent confusion and demonstrate the clear distinction between the two terms. The terms are used incorrectly and interchangeably throughout the document and should be updated to the appropriate term; in almost all instances the term should be inequities/equities.

The language used throughout the document has the potential to be strengthened and better framed from a strengths-based perspective. See a specific example under question 15.

Point 2.10 implies that engaging with Maaori and Pacific peoples is necessary for appropriate engagement, rather than ensuring that Maaori and/or Pacific peoples are actively involved in the research process and are part of the actual research methodology. We suggest strengthening the language used in this point.

## **Part two: feedback on sections**

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<sup>4</sup> See: World Health Organization: [http://www.who.int/topics/health\\_equity/en/](http://www.who.int/topics/health_equity/en/) and [http://www.who.int/features/factfiles/health\\_inequities/en/](http://www.who.int/features/factfiles/health_inequities/en/)

<sup>5</sup> See Braveman and Gruskin article (2003): <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1732430/pdf/v057p00254.pdf>. See also Whitehead (1992): <https://www.ncbi.nlm.nih.gov/pubmed/1644507>

## Ethical principles

### **9. The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).**

The content of this section is well-structured. We suggest this chapter should be considered a 'must-read' chapter for all those working in the health and disability sector, along with a range of other materials such as the Pharmac decision criteria for cost and cost-effectiveness considerations, as these Standards do not explicitly cover these issues. It would be useful to reference and hyperlink to such additional material.

### **10. The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.**

Both Te Ara Tika principles and bioethics principles are helpful principles in providing guidance for researchers. We recognise that all principles are equally and supremely important. However, we would like to see further commentary around potential conflict between various ethical principles and guidance on how to approach such conflict. For example, the decision to use tissue might be seen to belong to the whaanau or hapuu, not just an individual, and so the principle of respect for people (autonomy in making an informed choice) may conflict with the principle of whakapapa.

There is potential for both Te Ara Tika and bioethics to be applied more broadly. At present, most of the descriptions are referring to the relationship between the researchers, and participants, Maaori, the wider communities and/or other stakeholders. Many of the principles could be applied more broadly to the interactions between different research groups and health service funders and providers, in better coordinating their work to reduce duplication, share learning, and develop infrastructure that would support delivery of health services and future research. In the context of multi-morbidities as well as the complexity related to social and medical science research, there is an increasing need to design studies that capture a wide range of outcomes that are meaningful for the New Zealand population (e.g. whether preventing death from one disease instead of another without prolonging quality and quantity of life overall may be considered as a desirable outcome).

Cost and cost-effectiveness of research could be considered as part of the principles under beneficence, non-maleficence, and justice. Financial considerations and efficiency should be considered as part of the guiding principles of research, as often researchers have a role in stewardship of societal resources – both directly in their publicly funded research activities but also where their research will inform public sector decisions.

### **11. Do you have any comments on specific paragraphs of the section?**

The section on justice (page 18):

- 1) The definition of justice discusses reducing inequities and unjust inequalities. As mentioned in question 8, unjust inequalities *are* inequities, and so mention of inequalities should be removed from the sentence.
- 2) Additionally, as part of the justice principle, researchers should also consider if the research could increase inequities, and if that is the case, how that will be mitigated.

- 3) Working with Maaori in the research process is recognising the role of Maaori in co-governance as Te Tiriti partners (as per page 5). Working in partnership with Maaori can also be seen through the justice lens, and we suggest showing the links between Te Tiriti and justice in the justice section on page 18.

## Research involving Maaori

### **12. The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).**

This chapter is very important in the New Zealand research context. We believe that this chapter is much broader than merely 'research involving Maaori'. As said in point 6.11, *all* research in New Zealand is of interest to Maaori, and as such, we suggest that perhaps this chapter should be titled 'Research and Maaori' or equivalent phrasing, and point 6.11 should be discussed towards the start of the Standards. This shift in title and elevation of point 6.11 would emphasise that regardless of whether Maaori are participants in the research process or not, the research is of significance to Maaori.

This chapter does not mention the role of Te Mana Raraunga in Maaori data sovereignty, and the Standards as a whole only mention Te Mana Raraunga once. All researchers undertaking research in New Zealand need to be aware of the kaupapa of Te Mana Raraunga and what implications it has for their research.

Specific comments:

Point 6.7 says that researchers must collect ethnicity data. This point must apply to all research conducted in New Zealand, not just research involving Maaori (and as discussed earlier all research is of significance to Maaori). Ethnicity data collection is an important tool in measuring inequities between ethnicities, including between Maaori and non-Maaori. Thus, it is vital that researchers understand the Ethnicity Data Protocols for the health and disability sector and use them appropriately in their research.<sup>6</sup> Point 6.7 of the Standards should refer to the Ethnicity Data Protocols and should be considered the minimum expectation for research undertaken in New Zealand. This needs to be appropriately navigated by researchers who are part of multicentre international research.

The language used in points 6.8-6.10 and 6.27 again confuses the terms inequality and inequity. We recommend only discussing inequities in these points, as inequalities should have already been defined in point 2.8 (see our comments to question 8).

Point 6.19 with regards to international clinical trials says that researchers should adapt the protocol to the New Zealand context. We suggest that the Standards should add 'and it is expected that the lead New Zealand researchers involved will prioritise this' or equivalent phrasing.

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<sup>6</sup> See: Ministry of Health (2017): <https://www.health.govt.nz/publication/hiso-100012017-ethnicity-data-protocols>

Box 1 (page 23) says that the minimum expectation for research not involving Maaori is 'institutional review that confirms that exclusion of Maaori is valid and justified'. We suggest that the minimum expectations should also include self-assessment by researchers on how this research contributes to Te Tiriti partnerships. Maaori as tangata whenua have manaakitanga responsibility over all people in New Zealand<sup>7</sup> and researchers should be encouraged to explore how all research relates to Te Tiriti. This also fits in with the ethical principle of manaakitanga.

In Box 1, under research involving Maaori, it is unclear what this bullet point means: 'Maaori ethnicity data can be extrapolated from a general sample'. This needs further explanation to ensure the meaning of the statement is understood by all and is statistically and ethically sound.

### **13. The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.**

This chapter covers a broad range of ethical issues and principles pertaining to Maaori. One aspect we believe is not adequately covered is the role of Maaori governance in research/data taken overseas, as part of international collaborations. Researchers should be expected to consult with Maaori to ensure whaanau, hapuu, iwi, and Maaori communities understand implications of research/data taken overseas. We suggest the Standards make recommendations on how this should be managed.

## **Research involving Pacific peoples**

### **15. The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).**

This chapter covers useful information on research involving Pacific peoples. We believe that the introduction needs a brief explanation on why Pacific research is a priority in relation to equity. It needs to explain that this is different to the priority for Maaori, which is related firstly to Te Tiriti o Waitangi responsibilities and secondly, as part of that but also separately, to equity (i.e. the priority for Maaori would exist whether or not there were inequities in Maaori health).

The language used in this section needs to be improved so it is less deficit-framed. This needs to be reframed so that it is less about personal responsibility and focuses more on the institutional and structural barriers to access, for example, racism, poverty, unemployment, and a lack of appropriate support from social services. For example, point 7.10.

### **17. Do you have any comments on specific paragraphs of the section?**

Point 7.12 should be a 'must'. Any research with significant participation of Pacific peoples must have appropriate involvement of a Pacific researcher, expert, or advisory group.

## **Categories of participants**

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<sup>7</sup> See: Human Rights Commission (2011): [https://www.hrc.co.nz/files/9114/2369/9284/Te\\_Mana\\_i\\_Waitangi\\_booklet.pdf](https://www.hrc.co.nz/files/9114/2369/9284/Te_Mana_i_Waitangi_booklet.pdf)

**18. The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).**

Overall, we think this chapter is good, and in general we support the content. However, it is worth noting that our communities in Counties Manukau do not like the labelling 'vulnerable' or 'at risk'; this is deficitframing. We recognise it can be hard to consider alternative terms for 'vulnerable', nonetheless we suggest the Working Party considers a brief explanation recognising the limitation of the term 'vulnerable'.

## **Informed consent**

**21. The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).**

Overall, this chapter raises a number of important considerations with regards to consent in the context of health research.

The main weakness from our perspective is the discussion around consent and waiver for health information data. The section 'research without seeking consent' (page 45) needs to be more explicit in explaining how health information data is different to primary research data, and thus why the wavier is generally ethically and legally possible. As a minimum, this section needs to be hyperlinked to the health information section on page 88 in chapter 10. Please also see our comments under question 42.

It may be helpful to have a table/diagram to highlight how each of the sections are applied in different types of research. Many of the sections often are relevant for a specific type of research. It would also be helpful to provide some guidance for the grey areas in research and evaluation, and how the consent process could be applied (e.g. a programme that contains a number of assumptions in the intervention pathway).

**23. Do you have any comments on specific paragraphs of the section?**

Point 9.3 raises the point of collective mana; this is an important consideration, but it needs further explanation so that the term is better understood by all researchers.

We strongly support point 9.31 and encourage researchers to frame information sheets from the perspective of the participants, not the perspective of researchers or sponsors. This can be challenging when there is substantial information researchers believe participants need to know for consent to be informed, but in reality, they are not actually informed if the material is so long and complex that they are unable to engage with it. Advice from someone experienced in health literacy considerations may be useful and this could be stated.

## Research benefits and harms

### **24. The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).**

This section predominately focuses on discussing the balance of benefits and harms of the process of undertaking the research itself. There is also an ethical consideration of whether important benefits and harms as outcomes of the interventions being researched are adequately captured as part of the research project. In the context of increasing awareness of over-diagnosis and over-treatment, the inadvertent harms are often not actively captured in many diagnostic and interventional studies. As a consequence, the discussion about the benefits and harms of research outputs may not be balanced.

### **26. Do you have any comments on specific paragraphs of the section?**

Point 10.19 (particularly bullet point 4) in its current state is inconsistent with point 11.16. We suggest adding a caveat around how over-representation may be statistically justified.

We suggest point 10.25 should include processes for managing point 10.13 bullet point 2, around incidental, non-therapeutic, yet clinically relevant findings of research. This is mentioned again in point 14.52 bullet point 11; this is particularly important for interventional studies and we suggest hyperlinking these sections.



## Research development and design

### **29. Do you have any comments on specific paragraphs of the section?**

The section on equal explanatory power (page 58, points 11.15-11.17) is an important consideration. However, the draft document does not mention the Standards expected; we suggest adding a point about the Standards expected.

## Types of studies

### **30. The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).**

We recognise that the previous 2012 guidelines have been merged for ease of use, and note the argument that the previous guidelines created a false dichotomy between observational and interventional studies.

We appreciate that overarching ethical issues and principles are the same across all types of studies. However, we are uncertain if the one sole chapter on the various types of studies is adequate to discuss the unique issues pertaining to each type of study, and we question if combining the types of studies into one chapter is easy to use. We believe that there is potential for confusion on how to apply the Standards for the different types of studies.

Additionally, the chapter in its current form, mainly discusses ethical issues for interventional studies and there is little discussion of ethical issues for observational studies. We believe this chapter is not workable for researchers, as researchers conducting one type of study would still have to read the entire chapter to glean the ethical issues relevant to their type of research. For this reason, we suggest splitting this chapter into two sub-sections, one for interventional studies and one for observational studies, or creating two separate chapters. Both sections/chapters should then be clear about what Standards are applicable for what type of research, what the requirements for ethics approval are, and what the application process is.

### **31. The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.**

We suggest that the chapter should have more detailed commentary on observational studies; see our response to question 30.

We believe that the section on epidemiological and public health research studies (page 64) needs further work. It currently does not provide a Standard for that type of research and does not discuss the implications, benefits, and harms of this type of research for individuals and communities. We suggest further commentary for this

section, and to consider also showing links between this section and the sections on health information data (in chapters 9 and 14).

Additionally, we believe that the issue of consent in cluster randomised trials in communities needs further exploration (pages 65-66). For instance, if the intervention is an environmental manipulation, as can be the case in public health research (e.g. changing of the road layout to see effect on road traffic accidents), how could informed consent be sought from potential participants?

## Research conduct

### **34. The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.**

We recognise that these Standards are only applicable for research conducted in New Zealand. However, we realise that New Zealand-based researchers may conduct research overseas where the ethical standards may not be as robust as they are in New Zealand. We suggest the Standards make a comment encouraging New Zealand-based researchers conducting research overseas to uphold high ethical principles in other countries too, similar to what they would in New Zealand.

### **35. Do you have any comments on specific paragraphs of the section?**

Point 13.12 should be a 'must'. Researchers must register their clinical trials in the Clinical Trial Registry. They should also provide results of the study in the public database of the Clinical Trial Registry.

We support the Working Party for including point 13.13, and urge research and tertiary institutes to introduce new researchers and students to these Standards early in the curriculum.

## Health information

### **37. The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).**

The Population Health team at CM Health commends the Working Party for the chapter on health data. We fully support the decision to include a chapter on this as this is currently a grey area. We recognise this is a new section and believe this is a helpful start at describing and discussing the ethical issues around health information. However, in its current form, there are many gaps in the chapter and further work is required. We highlight three main issues with this chapter in our

response to this question. Further comments are in our responses to questions 38-43.

The largest area of problem in the chapter is that it does not explicitly differentiate between primary/specifically collected data and the use of existing health information data (also called health administrative data, and in the Standards described as databanks). While ultimately, they are both types of data and have some commonalities, they are collected in very different ways and have different ethical implications. For example, primary data is collected by the researchers themselves for a specific research question, whereas health information data is usually collected for administrative purposes, and at a later stage is used by an analyst or researcher to understand an aspect of the health of a population group.

The chapter mainly discusses ethical standards for primary data, with standards for health information data interspersed. We recommend defining the two different types of data at the start of the chapter, and then separately discussing the ethical issues and standards for each. This would make the chapter more workable and the ethical implications would be clearer, particularly for new researchers.

The second issue is related to data management and governance. We support the need for robust data management and governance processes. However, the Standards need to provide clarity that the discussion pertains to processes rather than actual management and governance groups, as we are cognisant that access to such groups can be barriers for small/independent researchers. This relates to points 14.17, 14.19, and 14.30. One of the key aspects to safeguard privacy is to have a consistently high standard of data security and ideally have systems in place to audit any possible breaches of privacy (e.g.

for DHBs to have built-in systems that would investigate clinicians who look up patients who are not directly under their care).

The third issue with this chapter is the commentary around data linkage. This is in two separate subsections, and it is not initially clear in the layout that they belong together. We have a number of points on data linkage:

- Point 14.27 on data linking by trained researchers needs a qualifier, otherwise this will lead to unnecessary administrative burden and cost. Data linking depends on the level of difficulty, for example deterministic linkage (e.g. based on NHI only) can be straight-forward, whereas probabilistic linking may require additional considerations. Points 14.37 and 14.38 pose a balancing act between the robustness of data linkage and the ability to validate data linkage and protection of privacy. It is important to acknowledge that data linkage is expected to improve over time, e.g. as duplicated NHIs are merged together. We suggest describing the context in which it would be helpful to reduce the risk of re-identification, as it is associated with significant administrative burden, and also makes subsequent improvement in data linkage much more difficult (e.g.

a list of merged NHIs is now available, but the existing data is no longer identifiable to allow the subsequent improvements).

- We believe that for point 14.26, the amount of data linked should be fit-for-purpose, as opposed to aiming for the minimalistic approach. Each variable can cross-validate in the context of linkage and so the data requested for each variable must be justified.
- Point 14.38 needs to clarify the data linkage step and also discuss the presentation of results. There needs to be an acknowledgement that loss of information may affect the quality of the data linkage.
- We believe that there is a missing sub-section/point on the ethical challenges of data linkage informing clinical actions by front-line clinicians. This is possible/not possible to varying degrees and there is debate on what the ethical obligations should be. Should a researcher who identifies a person with a mechanical heart valve not on anticoagulation (which will result in major clotting complications, such as a stroke or heart valve malfunction) based on administrative health data notify the clinician so the person can be appropriately managed?

### **38. The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.**

We have a range of comments on this chapter which we have made in questions 37 and 39.

We also recommend that the Working Party consider the Privacy, Human Rights and Ethics Framework developed by the Ministry of Social Development, and ideally draw connections between that piece of work and these Standards.<sup>8</sup>

### **39. Do you have any comments on specific paragraphs of the section?**

As discussed under question 37, there needs to be a clear separation between issues for primary data and health information data. Points 14.7-14.16 specifically apply to primary data collection, and should be addressed in a section separately on that topic.

Point 14.12: we believe that all identifiable data should have a higher level of protection, otherwise the term 'sensitive' becomes a value judgement call leading to an inconsistent approach.

Point 14.13 is presumably notwithstanding disclosure of information in case of an emergency, which we understand would be covered under other legislation, for example under the Health Act 1965.

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<sup>8</sup> See: Ministry of Social Development: <https://www.msd.govt.nz/about-msd-and-our-work/workprogrammes/initiatives/phrae/index.html>

The requirements to meet 14.12, 14.13 and 14.17 have to be considered as a whole. Some practical suggestions may be helpful as some of the requirements could be interpreted as contradictory. For example, it may not be possible to promptly report to the appropriate authority if an individual's life or health are in serious and imminent danger (14.13) if data is no longer identifiable (14.17). Does deleting of name and address etc. but leaving the NHI to store data in the least identifiable form meet the intent of 14.17? It would also be useful to clarify in what other circumstances (as noted above) would information related to a serious and imminent threat to public health, public safety, or the life or health of an individual be allowed to be disclosed where the possible disclosure has not previously been justified to the ethics committee? Some DHBs may have other disclosure processes in regard to reporting immediate harm.

Point 14.22 discusses that identifiable data may be sent overseas for research if there is appropriate consent. We believe there needs to be further discussion of this and that researchers need to consider this in the context of the principles of Maaori data governance. All research conducted in New Zealand is of importance to Maaori (see our comments under question 12), so there needs to be discussion on how the potential conflict could be managed.

Point 14.29 says that researchers should remove identifiers. We suggest this should instead say 'identifiable identifiers', so a researcher can keep track of the unique number and nature of individuals in the dataset.

There is a minor typo in point 14.37.

For point 14.42 on table 5, it would be better to say health conditions with high health care cost, as an example, as opposed to high social cost. While it may be intuitively helpful to highlight the association of specific health conditions with wider societal costs, at present there is very little comparability between conditions, because of difference in methods, and the issues of multiple counting of the same cost item are often not actively addressed (e.g. for people with multiple conditions). More importantly, the quantum of association is often inappropriately misinterpreted as causal links and implicitly assumes that there are proven interventions that would lead to cost savings of reported societal costs. As a consequence, the reported societal cost is often used to advocate for a specific area which may lead to imbalanced prioritisation of resources.

In table 6, there is mention of community discrimination; we are unsure if that means 'collective discrimination and stereotyping'? This needs to be clearer and more explicit.

We believe that points 14.46 and 14.47 are broader than the sub-section they are currently under. We feel these points should be adhered to in all circumstances.

The data quality comment in point 14.48 bullet point 2 can be an issue for a range of variables. The addition of 'other communities' in bullet point 6 of point 14.48 essentially means that this point includes all data and thus special measures apply to everything.

Point 14.57 should say potential benefits and harms.

## **Big data and new ways of using data**

**Use of data for research is becoming increasingly complex, involving linking across different agencies and use of algorithms or artificial intelligence. The ethical standards provide guidance when using data in order to increase public benefit while respecting people.**

**40. Do the standards present a reasonable balance between facilitating use of data while respecting rights to privacy and respect of people? Please provide feedback.**

The Standards do not provide enough information and discussion for researchers to consider the two opposing points (better use of data versus privacy).

The Standards have a higher weighting for efforts to protect privacy, thereby limiting the optimal use of data. There are a number of key steps that all researchers should rigorously follow to ensure privacy. However, some of the steps proposed, highlighted above (questions 37-39), would provide relatively marginal benefit over and above the key steps but result in substantial increase in administrative burden and associated costs and reduction in data quality and outputs. More attention is needed to consider the workflow of data linkage and how new data could be incorporated into existing datasets. For example, having safeguards to ensure secure NHI lookup processes to protect privacy may be more important than deleting the NHI off the research data.

The commentary around data identifiability is useful, and we strongly support maintaining privacy. However, we would like to reiterate that the section on health information data/databanks is currently weak and needs additional work (see responses to questions 37 and 41). Improving that section will lead to improvements in the advice provided around facilitating the use of data while respecting rights to privacy and respect to people.

Additionally, we have a specific comment around point 14.35. The three categories of data described in the Standards are a simple and useful way of understanding identifiability. However, it would be helpful to clarify the context when certain variables become identifiable. For example, we would like to point out that birth dates and employment details are not identifiable by themselves and require other

information/variables to make them identifiable. Likewise, NHI without a lookup tool (such as a patient management software tool) is not identifiable. It is worth acknowledging that some DHBs have audits in place to ensure that people looking up NHIs have genuine clinical and/or research reasons to do so. Auditors can monitor non-authorised access to NHIs. We suggest adding a footnote with such an explanation to remind patient management software users to be mindful of their NHI access. Prioritising the important steps to protect privacy, with more specific scenarios, would result in a more optimal balance between cost and robustness of results without compromising privacy.

## Databanks

### **41. The section is fit for purpose (the content of the section is helpful, clear, and relevant and workable).**

We support the inclusion of this new section and recognise the vital need of Standards in this area. Currently, this section requires further work to elaborate on the guidance provided.

We believe there is information pertaining to databanks/health information data/administrative data in other parts of the chapter on health data (chapter 14) that are relevant to this section, and we recommend collating all relevant information into one section for ease of use. As discussed in question 37, primary data commentary needs to be separate from health information data commentary, and the latter should be combined with commentary on databanks. Hyperlinks could be used helpfully across these sections.

### **42. The section covers all relevant ethical issues and or principles for health and disability research in New Zealand.**

The section touches upon the various types of databanks that exist. However, the information is limited to databanks in the health sphere. In reality, researchers will also be utilising databanks outside of the health and disability sector, and we suggest including a sub-section on the ethical debates in accessing wider databanks. The work in these Standards needs to align with the broader whole-of-government discussions on data, and not duplicating efforts (e.g. in the area of wellbeing).

The Standards do not mention the Integrated Data Infrastructure (IDI) developed by Statistics New Zealand. The IDI raises important ethical considerations and should be considered as part of these Standards. Researchers, particularly public health researchers, are already utilising the IDI and there needs to be clearer guidelines on navigating the ethical challenges present. For example, point 14.24 is a helpful instruction, but does that mean that everything in the IDI needs a waiver? We believe it would be useful to have some reference to the use of administrative data where

seeking specific consent is not possible, but the collection would be part of standard protocols. This could either be as an elaboration of point 14.24 or in a broader section on databanks (as suggested under question 41).

Chapter 14 also briefly touches upon the issue of waiver of consent for use of data (points 14.21 and

14.50). As we have raised earlier in this submission (question 21), the waiver of consent section needs to be elaborated upon. From a public health research perspective, we are interested to know whether this means that these waivers are always required; for example, how would this apply to an aggregated-level ecological study? Or, similarly, how do these waivers fit under the research and statistical purposes exception of the Privacy Act?

It is worth noting that all Ministry of Health data is collected for administrative purposes and most would be of secondary use in research. Would everyone who utilises administrative data require a waiver, even though they are dealing with aggregated data that is not identifiable at the individual level? For example, would a student requesting Ministry of Health data for an assignment require a waiver? This needs to be addressed either in this section or on page 45 in the informed consent chapter. We believe having a flow chart, table, or checklist would be helpful.

#### **43. Do you have any comments on specific paragraphs of the section?**

We believe there needs to be commentary on the systematic biases that may exist in using pre-existing data. This should ideally be in the new sub-section on health information data, or could go after point 14.45. We suggest something along the lines of 'researchers should be aware when using health information data for research purposes that the methods of collection of administrative data may result in systematic biases, which have implications for the results from the secondary use of data. This potential should be acknowledged by researchers when designing their research, so as to mitigate the impacts of these biases where possible, and in recognising limitations of the study when reporting research results.'

Point 14.59, we suggest the term 'may be able to' rather than 'can' when discussing significantly accelerating the improvement in the understanding of health etc.

#### **The end**

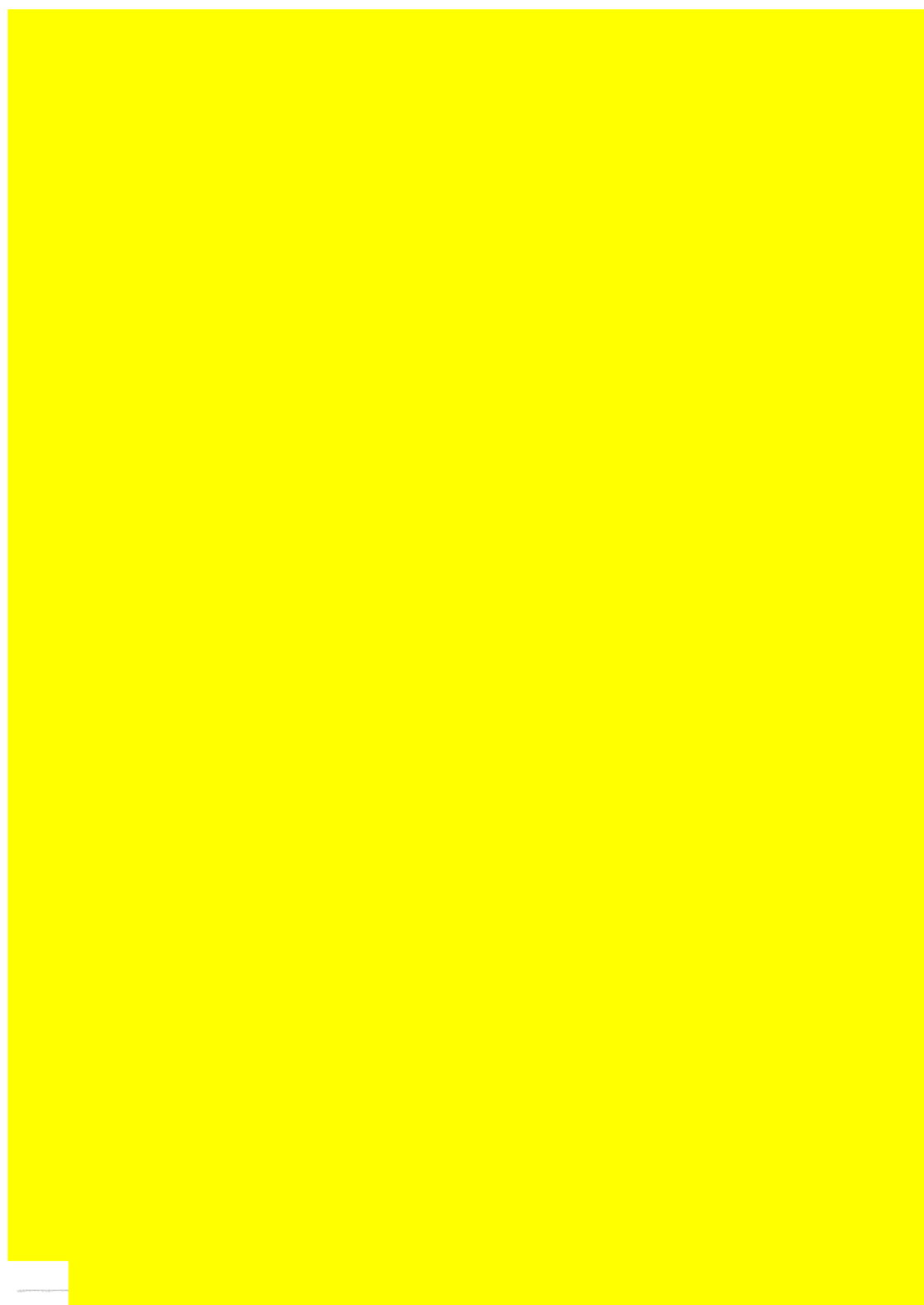
Thank you for considering our submission. We look forward to reviewing the next iteration of the Standards.

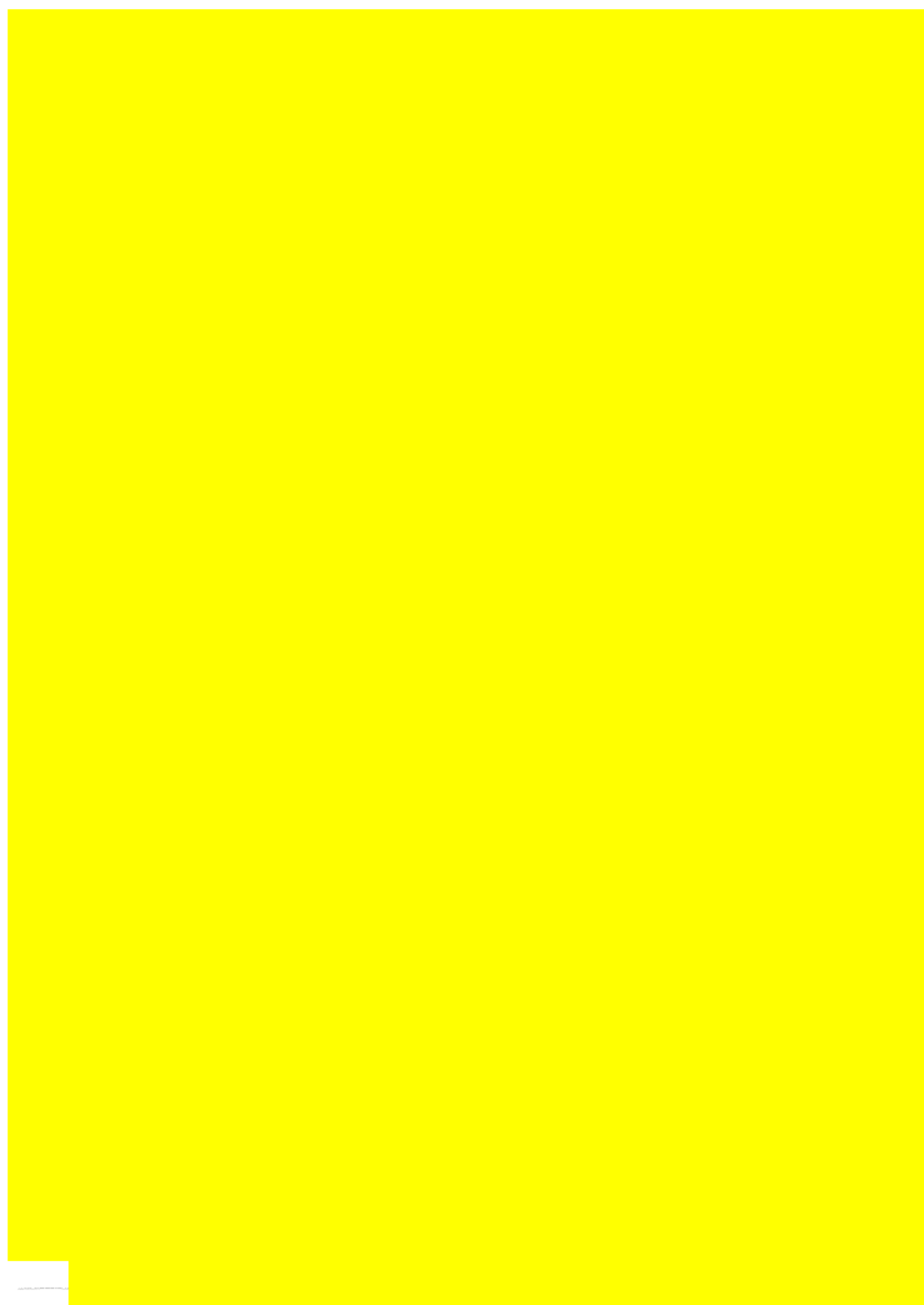


Response number

92

Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher
Publish response	You may publish this submission





Response number	94
Name	[redacted]
Organisation	Ministry of Social Development
Role	[redacted]
Interest group	Government
Publish response	You may publish this submission but anonymously

*Comments on the Draft National Ethical Standards for Health and Disability Research: Consultation Document prepared by MSD Service Delivery and Research & Evaluation teams*

28 September 2018

## General

In general the standards are clearly written and well set out. We support the move away from separate standards for observational and intervention studies, and support the integration of Te Ara Tika Principles.

## Scope

The definition of health and disability research in paragraph 4.3 is very broad, as are the statements of coverage in 4.5 and 4.6. In particular, the proposed definition encompasses social science research and social sector activity which does not necessarily have a health and disability focus.

This is useful in clarifying that social science research or use of data concerned with eg addressing disparities or improving wellbeing is important to the knowledge base required to improve people's health. And if the intention is to *allow but not require* eg research on social determinants of health or studies focussed on improving social wellbeing to come to HDECs and see itself as within the scope of these standards then that is a positive step.

However, if the intention is to *require* all such studies to comply with the standards and come to HDECs then this is problematic. It would place much of MSD and other government agencies' research and operational evaluation within scope as it often relates (directly or indirectly) to addressing disparities in employment, housing, income or benefit receipt, and improving wellbeing.

MSD Service Delivery and Research and Evaluation teams see the need for ethical oversight of such activities, but suggest that this requires a separate set of standards specific to the social sector, and ethics committee(s) with expertise relevant to the social sector.

We would welcome further work to develop ethical standards and committee(s) specifically for the social sector. MSD would be happy to support this process. The Ministry has established an independent Research Ethics Panel to strengthen its access to ethical review and has invited other social sector agencies to access the advice of the Panel.

Broadening the scope of review of HDECs without significant additional resource and standards and Committee membership that are fit for a wider scope is likely to swamp the committees and slow review. Timeliness of review is an important consideration for MSD. There are ethical risks in adding processes that significantly slow research and evaluation that is supporting policy and service improvement for MSD clients.

### **Non-research practices**

MSD often needs to test and iteratively develop a proposed intervention through a 'proof of concept' or 'prototype' stage before developing a model of practice or service that can be the subject of a large scale trial (with an associated impact study to assess effectiveness), or taken to scale without a trial.

The primary purpose of the proof of concept or prototype stage is to develop and refine the service design and delivery prior to testing or roll-out on a larger scale. For MSD, the focus of these activities could include establishing:

- the best way to refer clients or participants into the service
- the best way to communicate or coordinate between MSD, contracted service providers (which could include, but is not restricted to, health practitioners) and MSD clients
- whether the service as designed is acceptable and experienced as accessible and appropriate by MSD clients, including Māori, and if not, what modifications are required
- whether the proposed implementation is feasible
- whether any proposed training is meeting the needs of staff and clients.

For MSD, proof of concept and prototypes are not concerned with generating evidence on efficacy or effectiveness. Could the standards be revised to more clearly delineate these activities as 'non-research'?

Any assessment of effectiveness would take place within the context of a larger trial, which may fit the definition of research / evaluation and require ethical review (including by HDEC, where appropriate).

### **Innovative practice**

The proposed definition of 'innovative practice' is too narrow, and the description of its application is exclusively medical. This section is potentially highly relevant to our setting, and it is good to see it included. The proof of concept or prototype stage described above has many parallels with innovative practice, especially the greyiness of identifying when the time has come to formally research an innovative practice and what the nature of the research should be (4.16-4.20). MSD is always seeking ways

to improve the delivery of our services and our clients' experience. These activities often do not have a research focus at the outset, but may be the subject of an evaluation at a later point in time.

It would be useful if worked examples in a wider range of contexts could be included. Eg the application of paragraph 4.21 relating to fully informed consent for participation in innovative practices could be clarified. That there are service delivery contexts where informed consent for innovative practice may not be practical or appropriate (eg when the innovative practice is in the wording of a letter which needs to be sent in some form in any case, a public awareness campaign, the layout of an office or sequencing of a service, or use of text messaging to communicate with clients) could be acknowledged.

MSD's relationship with its clients is different to that of a health practice and a patient, or an academic institute and an academic study participant. MSD clients may receive a main benefit and this may come with obligations that are mandatory requirements (eg. active job search, attendance at appointments, and participation in seminars when required). Clarifying that informed consent for participation in an innovative practice may not be appropriate where participation in the relevant service is mandatory would be useful.

### **Informed consent**

In the sections on 'Research without seeking consent' (9.60) and 'Cluster randomised trials' (12.37), it would be useful to clarify the legal barrier referred to, and whether this applies narrowly to medical and scientific cluster randomised trials without individual consent, or whether it applies more generally to trials that seek to establish the effectiveness of government service delivery or marketing approaches that do not involve a health intervention, and/or are not intended to have scientific benefit, but are intended to have social benefit through improved service delivery and effectiveness.

Similarly, in 9.69 and 9.90 it would be useful to clarify whether there is any current legal barrier to applying the proposed two-step approach to research to establish the effectiveness of government service delivery and marketing approaches that do not involve a health intervention, and/or are not intended to have scientific benefit, but are intended to have social benefit through improved service delivery and effectiveness.

### **Secondary use of existing data – conditions for a waiver of consent**

The section on 'Secondary use of existing data or tissue samples' – 9.65 - recognises that studies using identifiable data without the informed consent if participants may be ethically justified, but there is no equivalent to paragraph 6.43 in the existing Observational Research guidelines.

Is 9.65 intended to replace the old paragraph 6.43? If so, there is a risk that the fourth bullet could be taken to trump all other considerations, and rule out a wide range of studies that would have social benefit where, under current guidelines, the

public interest in the study can be assessed as outweighing the public interest in privacy?

In or around this section, would it be useful to clarify the conditions for use of data for research without consent that apply in the case of non-identifiable data. These are referred to in 9.59, but could be made more clear.

## **Equipoise**

12.21 ends with the statement: ‘It may be justifiable to randomise participants to study arms that are not in equipoise if the better arm is not available as part of standard care and can only be offered to participants, by chance, in the intervention study.’

It would be useful to expand on this statement. In particular it would be useful to clarify whether funding or resource constraints could justify randomisation to generate evidence on cost effectiveness. Randomisation may allow the Ministry to generate on evidence on impact and cost effectiveness, which could contribute to improved service delivery.

## **The IDI, data banks and data linkage**

It is unclear whether the IDI would be regarded as a databank. It would be useful to make this quite explicit. The comments below assume that the IDI is regarded as a databank.

It is notable that the sections relating to data linking and databanks are treated quite separately. However it is hard to apply these standards in relation to the IDI given that the design and structure of the IDI incorporates elements of both data linkage and storage within a databank.

Examples of this are:

- 14.26 (data linking standards) states that the amount of data linked **must** be the minimum required to answer the research question(s). But this would seem to preclude linkage to the IDI given that it is not possible to link data to only some datasets but not others. Of course this may be intentional – but if so it would be good to confirm this.
- The section relating to databanks sensibly recognises the important role of robust data governance. But the wording of this section sometimes suggests that the governance sits with a single party, when (in the case of the IDI) it is distributed. For example, section 14.62 states that “a databank must have a governance structure in place, which includes...” and then lists some processes that would sit with StatsNZ (e.g. physical security measures) and some processes that would sit with a potentially diverse range of data suppliers (e.g. procedures for quality control of data collection, participatory engagement with patient groups).
- 9.39 and 9.40 on consent requirements for databanks – when applied to the case of survey data being linked to the IDI, the existing wording imagines a static collection where the nature of the data and linkages can be described to

a consenting surveyed individual, but the IDI is dynamic, with constant addition of new data sets, and potential for, once non-identifiable, relationships to other, non-consenting, non-surveyed individuals to be studied.

These examples suggest it may be useful in the revised guidelines to develop a dedicated section that treats the IDI as a special case. This more explicit guidance would help avoid some of the ambiguities above and provide an integrated set of principles and considerations that need to apply when linking health research data to the IDI.

The report refers to various pieces of relevant legislation that need to be considered. These references should include the Statistics Act (1975) given that it provides the legislative framework for the IDI and has particular implications for privacy over and above the more general provisions set out in the Privacy Act.

### **Co-design or participatory research designs**

Co-design is about addressing the power imbalances created by traditional service design, not perpetuating them. Section 12.29 fails to reflect this and we suggest NEAC revise this section in consultation with subject matter experts on co-design.

A good co-design approach may require significant time in the 'design' phase prior to formal trial and evaluation. This design phase could involve an iterative build, test, learn and refine cycle, where participants (including MSD clients) work collaboratively to improve the proposed intervention. While MSD is clear regarding our ethical obligations to clients and acknowledge the inherent power imbalances, we note this is the key reason for MSD introducing a co-design approach into our work. Staged ethics applications are not a practical solution, particularly when it is questionable whether the proposed intervention will meet the definition of research (e.g. MSD might co-design improvements to existing services with our clients).



Response number	95
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Research Funder and Consumer
Publish response	You may publish this submission but anonymously.

## Individual Feedback

I acknowledge just how much thought has been given to this document by many people. Having attended the workshop on 3 September I also wish to acknowledge the level of understanding of the issues which has resulted in this document being in its current form.

In my view the Standards are comprehensive, helpful and relevant. In some instances, it would be helpful to provide more clarity, tweak some wording and close some gaps. Please review my suggestions below.

### I. Examples where more clarity is needed:

#### 13.81 Informed and Voluntary Consent and Waivers

Obtaining the informed and voluntary consent of participants is the default starting point in these standards. In limited circumstances, aspects of the consent process may be modified or the requirement to obtain consent may be waived.

*The storing of breast tumours and tissue is important for breast cancer patients. It appears over time that consent may be waived. Given it may take up to 10 and even 20 years before a secondary cancer is identified the description provided for waiving of consent suggests that the waiver condition could result in someone learning too late that their tissue has been used for other purposes? It is clear a waiver exists but under what conditions? The waiver condition appears to override the default starting point. If a waiver occurs upon death, then I would accept the waiver.*

#### 10. Research Benefits and Harm

*The document appears to unnecessarily emphasize harm rather than also continuing to emphasize the opportunity or benefit available. There is a slight paternalistic feel.*

*I am aware there may be risks where new therapies are offered and it is important to manage the risk of harm in those instances (detailed strongly in Breast Cancer Aotearoa submission). Not all research however carries a risk of harm. Where the intervention is one relating to data or a blood test, risks may be mitigated.*

*As outlined in 13.80 researchers should provide participants the choice of opting out of receiving results of analyses that are not clinically significant or for which treatment is not available. It may be appropriate to offer this choice to participants at two points of the research: when they initially enrol in the research study and/or after the results are available. It is important to signal to participants when they enrol that they will be*

routinely asked to reaffirm their decision at the second point; this request will not be because of the nature of their results.

*This is an important paragraph for those who may receive information which is not fully understood and for which treatments may not exist. This step provides an excellent way to handle a wide spectrum of participants and their desire or willingness to receive information/results.*

*I suggest that this paragraph should be outlined much earlier in the document and not be left to page 79.*

13.74 *As long as the perception of harm is not overly paternalistic. See comments to 10 above.*

#### 16. Biobanks

*Are there any circumstances where tissue may be used for individual reasons once gifted? This is not clear and needs to be clarified.*

*If a biobank is closed, is the donor (if still alive) informed and asked what should happen to their tissue?*

#### II. Suggested wording

13.43 ..... please add *creating knowledge for researchers and participants*

8.32 .... after proposed treatment add *and its potential consequences*

### 3. Gaps

- i. Commentary p 29. Potentially vulnerable participants in research  
Please add *People with poor health literacy*
- ii. 9.33 *I accept that description of therapeutic misconception but would also welcome acknowledgement that researchers may also withhold providing information when they feel they do not have all the answers, particularly when some participants may have no issue working with that ambiguity. We have suggested how risks in relation to this issue may be managed in 1.10 above*
- iii. *Ethical Standards*

*Is it an ethical right for New Zealanders to have access to clinical trials/research?*

*If it is who is responsible for resolving this dilemma? How will it be resolved?*

*The issue faced is that we lack mobility between and across DHB's.*

*This document which is a National document is silent regarding the challenges of recruiting for niche clinical trials at a local level. In New Zealand while we lack mobility of participants across and between DHB's we struggle to get the required*

*numbers to fill trials in required time frames and in addition we are depriving participants of the opportunities such trials present and the economic/social benefits that may also ensue.*

Response number	96
Name	[redacted]
Organisation	University of Otago, Wellington
Role	Senior Research Fellow
Interest group	Researcher
Publish response	You may publish this submission

## Introduction

We are researchers in the Element group in the Department of Public Health, University of Otago, Wellington. We are experienced in research with people with experience of mental illness, ranging from large quantitative studies, to small qualitative studies. [redacted] is a qualified medical doctor and epidemiologist, and [redacted] is a social science researcher with an emphasis on the lived experiences of people with experience of mental illness.

2.8 (and 6.8) definition of health inequities – we suggest a simpler and clearer definition of health inequities, eg “*Health inequity* refers to those inequalities in health that are deemed to be unfair or stemming from some form of injustice” (Kawachi 2002, JECH 59(9) p. 647) or “differences which are unnecessary and avoidable, but in addition are considered unfair and unjust” (Whitehead 1992, International Journal of Health Services 22 p. 431). It would also be clearer to use the same definition in both places.

## Chapter 8

### Vulnerable participants

#### 8.2-8.14

We support the explicit acknowledgement that research with vulnerable groups is necessary to answer questions related to those groups (8.2). We suggest that this point could be strengthened by an acknowledgement that such research is often crucial in reducing the health inequities experienced by these groups.

We support the explicit recognition that researchers should not exclude participants simply because they belong to a group traditionally considered vulnerable (8.3). We note that as a large proportion of the population will experience mental illness at some stage in their lives, it seems impracticable to categorise them all as vulnerable. We would therefore suggest that an additional point about vulnerability varying over time be added. People may be considered vulnerable at some stages in their lives but not in others. Once they have been categorised as vulnerable does not mean they will always be vulnerable. This means that a person with a history of mental illness should not be categorised as vulnerable unless there are present indications that they need to be so.

We support the explicit recognition that researchers should assume capacity unless they have reasonable grounds for believing otherwise, (8.7) and again note that lack of capacity at one time does not imply continued lack of capacity.

8.18

The term 'psychiatric disease' is inappropriate; mental illness or distress should be used instead

8.24

Vulnerability to being over-researched needs to be balanced with the right to be involved in research that could potentially improve the health status of the vulnerable group. Researchers may also shy away from research involving vulnerable groups because it is seen as too difficult to meet ethical standards, denying people of a potential to contribute to improving treatment of health conditions.

8.25

Using an independent person to undertake the consent process: We suggest that an 'independent person' should not include a person from the potential participant's clinical team, even if they are not part of the research team. The power imbalance is also present in the clinician/patient relationship.

Chapter 9

9.34

The potential length of the participant information sheet may put off potential participants, including those who are most vulnerable and most likely to experience health inequities. Ethics Committees will need to provide example information sheets and consent forms (much as they do at the moment) using different types of studies as examples.

9.65

We support the inclusion of a requirement for consultation with relevant groups where data is to be used without explicit consent.

Chapter 12

12.29

It is pleasing to see a section devoted to co-design in research. Acknowledged in 12.29, we echo the need for more guidance for ethics committees in how to handle ethics issues related to this type of research. Our experience has shown that Ethics Committees do not handle participatory research design well.

Chapter 13

13.20-13.24

Using clinicians to approach potential research participants is common in mental health research, as a way of ensuring people are well enough to participate. However, the risks of such approach need to be stated, beyond the risks to privacy

implied in 13.21. These include putting undue pressure on people to participate (or not participate) due to the power imbalance between clinician and participant; risking confidentiality (the clinician will know who the potential participants are); and the clinician making decisions about who is a suitable candidate for the research, potentially biasing the study if they exclude participants because they may think they are too difficult to involve, or if they disagree with their viewpoint, or they think the person may not be interested (without asking them).

## Chapter 14

We support the definitions of three types of data relating to its identifiability. We would like to see these three types of data referred to throughout this section, particularly in the 'standards' section. For example the requirement to gain a waiver of consent to use data only applies where data is identifiable or re-identifiable.

Previously the National Ethics Committees have not considered applications where the data is wholly non-identifiable. However this section seems to suggest that there are circumstances where non-identifiable data use poses ethical concerns, eg where data is linked and/or could increase the stigmatisation of a group. Moreover, some of the considerations in the standards section apply to all research with data, whether or not it is identifiable, including balancing benefits and harms, training of data collectors, data storage, Māori governance etc. Some more clarity about the different risks and requirements for different types of data would be helpful.

Response number	97
Name	[redacted]
Organisation	[redacted]
Role	[redacted]
Interest group	Researcher
Publish response	You may publish this submission

## Submission to NEAC

### Draft National Ethical Standards for Health and Disability Research: Consultation Document

#### Research in children and young people:

I wish to provide some feedback on the guidelines that concern research with children and young people. My two main concerns are 1) the assumption that young people under 16 years cannot provide informed consent and 2) what constitutes a paternalistic attitude towards children/young people in this section of the document. The relationship of researchers to children/young people as research participants should be one of respect for children's agency while at the same time acknowledging the power imbalances between adults and children, which can put children/young people at greater risk when engaging in research.

#### Informed Consent

The ethical issues surrounding children's consent to *treatment* are a useful basis on which to shape consent to clinical/medical research that involves children.

In New Zealand, the right to make an informed choice before receiving services or participating in research is central to the Code of Health and Disability Services Consumers' Rights. The Health and Disability Commission has stated that: "The fundamental premise of the Code is that services cannot be provided without a consumer's informed consent."

(<https://www.hdc.org.nz/resources/publications/search-resources/articles/without-informed-consent-tread-warily-to-protect-the-persons-legal-rights/>).

Under this Code, Right 7, Right to make an informed choice and give informed consent, states:

2) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent. (3) Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.

This right applies to all children and young people. There is no age limit to this right. While young people over 16 years of age can give consent to health procedures

under the Care of Children Act (2004), the law is silent on those under 16 years of age. Under common law (following Gillick v West Norfolk Area Health, 1986) and the Code of Health and Disability Services Consumers' Rights, young people under 16 years of age are not automatically prohibited from giving consent. If deemed competent they have the right to consent to or refuse treatment. The policies and guidelines for practitioners in this area suggest that imposing an age limit is not practicable or preferable, and that children and young people should be given the opportunity to provide informed consent if they are deemed competent.

As there is no age limit to this right, even very young children have the right to be consulted: Right 7 (3) states: Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.

*While decisions concerning participation in clinical research are not the same as those that might be made about health treatment, the two cases are similar. For this reason, if an (arbitrary) age limit of 16 years is being selected for consent purposes, there needs to be a) a statement that this age limit is being chosen by NEAC, and b) some justification for why 16 years.*

If it is decided that participation in clinical trials for those under 16 years of age requires parental consent, then in view of the right of children/young people to give consent/refuse treatment, it would be good practice to require that a (competent) young person (under 16 years) also gives informed consent to participate in research trials, *along with* parental consent.

*Clear/sustained dissent by children/young people should be respected, in all cases.*

Paragraph 8.27 of the Draft National Ethical Standard for Health and Disability Research Consultation Document states: 'Research involving children and young people raises particular ethical concerns about:

- Their capacity to understand what the research involves and, therefore, *in the case of adolescents [my italics]*, whether their consent is sufficient for them to participate in research.'

If the age limit of 16 years is to be applied, then it should be assumed that those over 16 years of age have the capacity to understand, and the standards for health treatment should apply i.e. every consumer is presumed competent to give informed consent unless there are reasonable grounds for believing otherwise.

For all children/young people, the onus should be *on the researchers* to ensure there are careful processes around obtaining informed consent; that information is clear, provided in a way that makes sense to the potential participants, that their consent is genuine and not given to please adults, and so on. Following the case for consent to medical treatment, this bullet point might state instead: 'When research includes children and young people as participants, researchers need to be clear that the child/young person is competent to provide consent to participate in the research and that information is provided in a way that is appropriate for the age group concerned.'

Paragraph 8.28 states (bullet point 3):



- 'If the child is under 16 years old and lacks the necessary capacity to give legally effective consent, the researcher gets consent for the child to participate from their parent or legal guardian.'

And bullet point 5 states:

- 'If a child turns 16 during the course of a study, the researcher seeks their consent to continue participation.'

These both imply that those under 16 years of age should be treated differently from those over 16 years of age, and that there is some form of 'legality' relating to consent. As argued above, if the Guidelines for participation in research intend to introduce an age limit of 16 years for informed consent, then that needs to be stated separately, and should be justified, as it differs from informed consent for health services. It is not clear what 'legally effective consent' means; for health services, a *competent* child/young person of any age has the right to consent to treatment. The phrase 'legally effective' is redundant.

Similarly, Paragraph 8.32 states: '...If during the study the child reaches the capacity to give legally effective consent, the researcher must get the child's consent, which will replace their parents' consent on their behalf'.

The words 'legally effective' in the phrase 'legally effective consent', are redundant.

Paragraph 8.30 which states: 'However, participants aged 16 years or older must provide their own informed consent,' I suggest that *all competent children/young people* should provide informed consent.

Paragraph 8.31: 'Different levels of *maturity* [my italics] and a person's corresponding capacity to be involved in the decision include':

And (bullet point 4) states:

- 'Young people who are *mature* [my italics] enough to understand and consent, and are not vulnerable through *immaturity* [my italics] in ways that warrant the need for additional consent from a parent or guardian.'

This implies that consent depends on 'maturity', which is another concept entirely and is unnecessarily introduced. As in the case of health services, consent to participate in research should require only that children are *competent* to give consent. (The Medical Council of NZ outlines *competence* briefly: "Generally, a competent child is one who is able to understand the nature, purpose and possible consequences of the proposed investigation or treatment, as well as the consequences of non-treatment."<sup>9</sup> The level of competence required may differ depending on the degree of risk or complexity of the treatment/research.)

The addition of 'maturity' is patronising and it also exemplifies a patronising tone that permeates much of this section on research in children and young people. For example, paragraph 8.26 states:

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<sup>9</sup> Medical Council of NZ, "Information, choice of treatment and informed consent".  
<https://www.mcnz.org.nz/assets/News-and-Publications/Statements/Information-choice-of-treatment-andinformed-consent.pdf>

‘Children are not simply small adults. Research involving children and young people is important to understand their unique physiologies and health and disability needs. However, the manner in which the research is conducted should acknowledge that additional protections are necessary for the safety and emotional and psychological security of the child or young person.’

Acknowledgment of children’s agency and treating them with dignity would restate that paragraph along the lines of: ‘The manner in which the research is conducted should acknowledge the power imbalance between adults and children that place children at risk of harm from adults, including researchers.’

Paragraph 8.34: ‘Researchers should keep research data on the child participants for 10 years after the child has reached the age of 16 years. Children have the right to withdraw consent to the continued use or retention of personally identifiable health research data (and tissue) once they reach the age of 16 years.’

Once again, there is an implication that conditions for consent change at 16 years of age. As stated above, this deviates from consent for health services, and if that is intended it needs justification.

Moreover, it is difficult to see why data on child participants should be kept for 10 years (after they reach age 16). If consent has been obtained as part of good, ethical processes then there should be no need to hold data for such a long period, which is more likely to put participants at further, rather than lesser risk.

Paragraph 8.36: ‘Researchers need to *protect* [my italics] children if study participation involves the disclosure of sensitive information, such as sexual activity, drug use, or abuse...’. The word ‘protect’ is paternalistic. Research that involves disclosure of sensitive information, whether participants are adults or children, should take extra care that participants are not harmed and it may be necessary to include additional research protocols around such things as ‘secure data’, ‘good information’, ‘informed consent’ and ‘avoiding harm’. Rather than suggest *protecting* children (or other participants), which is paternalistic, the requirement should be that researchers undertake good ethical practice.

In relation to this, I suggest that if participants (including children) may be likely to disclose information that they, or someone else, is at risk of harm, and that would normally require a researcher to inform someone in authority (e.g. social workers or police), then the participant is told this beforehand, so the participant can then make an informed decision as to whether or not to disclose. (See also paragraphs 14.13 – 14.16)

Paragraph 8.28 states (bullet point 3): ‘... the researcher gets consent for the child to participate from their parent or legal guardian’. For Māori participants, where whānau has collective responsibility for a child, it may be the case that decision-making needs to be shared with other members of the whānau. For Pacific participants, it may be necessary to involve an extended family group or community in decision-making.

‘Consent in Child and Youth Health: Information for Practitioners’, which provides both legal and ethical information concerning consent to treatment and the

participation of children/young people in research, is an excellent resource for practitioners/researchers who are working with children.

The section on health-related research is particularly helpful (p. 23).

(<https://www.health.govt.nz/publication/consent-child-and-youth-health-information-practitioners>)

Name	[redacted]
Organisation	Te Rūnanga o Ngāi Tahu
Role	[redacted]
Interest group	Other, Iwi
Publish response	You may publish this submission

### Executive Summary

- 1.1 Te Rūnanga o Ngāi Tahu (“Te Rūnanga”) welcomes the opportunity to comment on the draft National Ethical Standards for Health and Disability Research (“the Standards”). Te Rūnanga would like to acknowledge the National Ethics Advisory Committee (“NEAC”) for their work in creating these draft standards.
- 1.2 Te Rūnanga is committed to improving the health of Ngāi Tahu whānui, ensuring our people flourish and are positively represented in health and wellbeing statistics.
- 1.3 Te Rūnanga would like to commend the NEAC for the clear understanding and subsequent explanation of the Treaty of Waitangi. It was encouraging to see the description of the Treaty principles as partnership, participation and protection.
- 1.4 Te Rūnanga support the use of the two sets of ethical principles and the partnership approach that it demonstrates. The four pou of tika, manaakitanga, whakapapa and mana are well defined and align to some of the core values of Ngāi Tahu.
- 1.5 Te Rūnanga appreciate that the Standards have stated the responsibility of all researchers and research to Māori as tangata whenua and Treaty Partners. Te Rūnanga recognise the important role that researchers and research organisations have in addressing the persistent inequality faced by Māori. It is important that the current inequities faced by Māori in terms of health are not carried with us into the future.
- 1.6 Te Rūnanga recommend that all information regarding Māori is able to be identified at an iwi level. This will allow iwi, such as Ngāi Tahu, to be able to fully understand and utilise the health and disability research to enhance whānau wellbeing.
- 1.7 Although Te Rūnanga are supportive of a large proportion of the Standards, there are a range of other minor concerns for Te Rūnanga within the Standards, which we address in each section of this response.

### Te Rūnanga o Ngāi Tahu

- 2.1. This response is made on behalf of Te Rūnanga o Ngāi Tahu. Te Rūnanga is statutorily recognised as the representative tribal body of Ngāi Tahu whānui and was established as a body corporate on 24th April 1996 under section 6 of Te Rūnanga o Ngāi Tahu Act 1996 (the Act).
- 2.2. We note for the NEAC the following relevant provisions of our constitutional documents:

Section 3 of the Act States:

“This Act binds the Crown and every person (including any body politic or corporate) whose rights are affected by any provisions of this Act.”

Section 15(1) of the Act states:

“Te Rūnanga o Ngāi Tahu shall be recognised for all purposes as the representative of Ngāi Tahu Whānui.”

- 2.3. The Charter of Te Rūnanga o Ngāi Tahu constitutes Te Rūnanga as the kaitiaki of the tribal interest.
- 2.4. Te Rūnanga respectfully requests that the NEAC accord this response the status and weight due to the tribal collective, Ngāi Tahu whānui, currently comprising over 61,000 members registered in accordance with section 8 of the Act.
- 2.5. Notwithstanding its statutory status as the representative voice of Ngāi Tahu whānui “for all purposes”, Te Rūnanga accepts and respects the right of individuals and Papatipu Rūnanga to make their own responses in relation to this matter.

### **Te Rūnanga Interests in the national ethical standards for health and disability research**

- 3.1. Te Rūnanga is committed to improving the health and wellbeing of our people, ensuring our iwi are represented positively in health statistics, and to that end we support the Standards to the extent that research conducted in accordance with the Standards will provide positive outcomes for our Ngāi Tahu whānui.
- 3.2 Te Rūnanga notes the following interests:

#### ***Treaty Relationship***

- Te Rūnanga has a specific interest by virtue of the Ngāi Tahu Claims Settlement Act 1998 (the Act) that provides for Ngāi Tahu and the Crown to enter a new age of co-operation. An excerpt of the Act is attached as Appendix One.

#### ***Manaakitanga***

- Te Rūnanga and Ngāi Tahu whānui also have a cultural responsibility to ensure the well-being of others in the Ngāi Tahu takiwā particularly in supporting Māori health and research aspirations.

#### ***Kaitiakitanga***

- In keeping with the kaitiaki responsibilities, Te Rūnanga has an interest in ensuring that there is equitable access to the factors that enhance our ability to thrive as a people in all aspects of wellbeing. This principle reflects the commitment to working together to achieve shared goals and objectives.
- Te Rūnanga is committed to supporting Ngāi Tahu whānui health outcomes. This is achieved by recognising our role as a Tiriti partner to advocate for Governmental responses that are aligned to the needs and aspirations of our whānui.

- At all times, Te Rūnanga is guided by the tribal whakataukī: “Mō tātou, ā, mō kā uri ā muri ake nei” (for us and our descendants after us).

### **Whānaungatanga**

- Te Rūnanga has a responsibility to actively promote the wellbeing of Ngāi Tahu whānui. The Act provides for Ngāi Tahu and the Crown to enter into a new age of co-operation. An excerpt of the Act is attached as Appendix One, as a guide to the basis of the post-Settlement relationship which underpins this response.
- The Crown apology to Ngāi Tahu recognises the Treaty principles of partnership, active participation in decision-making, active protection and rangatiratanga.

## **RESPONSE TO QUESTIONS:**

### **General feedback**

- Te Rūnanga would like to commend the NEAC for the understanding and explanation of the Treaty of Waitangi. The description of the Treaty as the “Foundation for the people of New Zealand’s enduring relationship as equal partners” and the description of the principles as partnership, participation and protection, was heartening to read. Te Rūnanga express our appreciation in the appropriate use of Māori experts’ knowledge and skills in the formation of these Standards.
- The responsibility of the research and researchers to Māori is encouraging to see, as we recognise the importance that researchers and research have in addressing the persistent inequality faced by Māori. It is important that those undertaking research in New Zealand understand this significant responsibility, and the importance their research can have for health in Māori communities and in addressing the current inequities in Māori health. Te Rūnanga appreciate the explanation of this in the Standards.
- Te Rūnanga support the consistency with the New Zealand Health Research Strategy and the recognition of He Korowai Oranga and its Vision Mātauranga principles.

### **Sections:**

#### **5. Ethical Principles**

- Te Rūnanga support the use of the two sets of ethical principles and the partnership approach that it demonstrates. The four pou of tika, manaakitanga, whakapapa and mana are well defined and align to some of the core values of Ngāi Tahu. The explanation that the two sets of principles are complementary in nature, but do not necessarily have to align.
- Te Rūnanga appreciate that the 2010 Te Ara Tika Guidelines have been utilised in the development of the principles. Te Rūnanga mihi to Professor Khyla Russell for her mahi in the development of these guidelines.

#### **6. Research Involving Māori**

- Overall, Te Rūnanga support the Research Involving Māori section particularly section 6.3 – 6.6 and 6.14. Te Rūnanga strongly support the inclusion of the rights of indigenous people in New Zealand, and the use of the Mataatua Declaration and the United Nations work to support this.

- Te Rūnanga appreciate that the Standards have outlined the responsibility of all researchers and research to Māori as tangata whenua and Treaty Partners. It is important that the current inequities faced by Māori in terms of the health and wellbeing are not carried with us into the future.
- Te Rūnanga recommend strengthening section 6.19 in relation to international trials in New Zealand. To say “It is important that research must adapt to the protocol in the New Zealand context”. Te Rūnanga believe any research conducted in New Zealand must abide by the Standards and recognise the role that Māori have as Treaty Partners.
- Te Rūnanga strongly recommend all information regarding Māori is able to be identified to an iwi level. This is crucial for iwi to be able to utilise these processes to better understand and address the needs of its people.

## **8. Categories of participants**

- In regards to vulnerable people it is important to note that vulnerable people are a product of the environment they live within, and the term vulnerable can disempower these groups. Whānau do not consider themselves ‘vulnerable’. Te Rūnanga suggest rewording this section.
- Te Rūnanga acknowledge the effort to manage power imbalance in the Standards.

## **9. Informed Consent**

- Te Rūnanga again recommend here that all information regarding Māori is able to be identified to an iwi level.
- The unspecified future use of tissue is a concern for Te Rūnanga. When giving consent, it is crucial that whānau are involved in the decision making process with each use of their tissue.
- Te Rūnanga recommend that there is a te reo Māori consent version available, which includes the regional dialect.

## **10. Research with benefits and harms**

- It is important that researchers are aware when involving Māori in their studies that the risks they are assessing are not just to that individual but to their whole community. It is also important that when evaluating the risks and benefits of a study to Māori, that Māori are making these decisions. Te Rūnanga recommend that the Standards clearly incorporate decision making for Māori by Māori.

## **11. Research with Development and design**

- Te Rūnanga recommend the addition of a point in the Protocol (11.11). We suggest that specific regard must be given to Māori outcomes (as tangata whenua and Treaty Partners), as to date we have been excluded from the full benefits of research into health and disability and are currently experiencing significant inequalities in health.
- Te Rūnanga suggest for 11.21 the addition of a point that research is demonstrating both sets of principles.
- Te Rūnanga suggest rewording point 11.22 to say “Peer review must include considering cultural relevance and appropriateness.”

## **13. Research Conduct**

- Te Rūnanga strongly commend the use of the Te Ara Tika guidelines.
- Section 13.3 is important to Ngāi Tahu, as excellent practice involves the lasting relationship established by the researchers with the Māori community prior to consultation and after the research has been undertaken.
- Te Rūnanga support providing a koha as it is important that whānau are recognised for their expertise.
- Te Rūnanga recommend the addition of a cultural safety provision into the safety protocol. It is important when researchers are going into a Māori environment, e.g. marae, they are prepared with the kawa and tikanga of that particular area.
- Te Rūnanga agree with section 13.73 that it is important that researchers are framing their results and findings in ways that are easily understandable and accessible to whānau involved.
- Te Rūnanga agree with section 13.76 that having localised relationships and connections is a very important part of the research. Having these connections allows researchers to better understand the needs of that community.

#### **14. Health Data**

- Te Rūnanga strongly support section 14.20 that Māori have rights and interests in relation to data, and it is crucial that Māori are governing their own data.

#### **15. Human tissue, 16. Bio Banks, 17. Research with Stem Cells**

- It is important to note that for Ngāi Tahu, as for other iwi, human genetic material (te ira tangata) carries whakapapa, and is therefore tapu. This places on individual iwi members an additional layer of ethical responsibility towards the iwi collective in respect of the way in which their genetic material is provided to third parties.
- Te Rūnanga affirms the right of iwi members to make their own, individual choices in respect of their personal genetic material.
- Te Rūnanga requires that mana whenua must be notified of the policies and practices relating to storage and disposal of human genetic material in their iwi region, regardless of whether this belonged to deceased Māori individuals or non-Māori, due to the significant cultural and spiritual implications this has.



## APPENDIX ONE: Text of Crown Apology

The following is text of the Crown apology contained in the Ngāi Tahu Claims Settlement Act 1998.

### **Part One – Apology by the Crown to Ngāi Tahu**

#### **Section 5      Text in Māori**

- Kei te mōhio te Karauna i te tino roa o ngā tūpuna o Ngāi Tahu e totohe ana kia utu mai rātou e te Karauna—tata atu ki 150 ngā tau i puta ai tēnei pēpeha a Ngāi Tahu arā: “He mahi kai tākata, he mahi kai hoaka”. Nā te whai mahara o ngā tūpuna o Ngāi Tahu ki ngā āhuatanga o ngā kawenga a te Karauna i kawea ai e Matiaha Tiramōrehu tana petihana ki a Kuini Wikitoria i te tau 1857. I tuhia e Tiramōrehu tana petihana arā: ‘Koia nei te whakahau a tōu aroha i whiua e koe ki runga i ēnei kāwana... tērā kia whakakotahitia te ture, kia whakakotahitia ngā whakahau, kia ōrite ngā āhuatanga mō te kiri mā kia rite ki tō te kiri waitutu, me te whakatakoto i te aroha o tōu ngākau pai ki runga i te iwi Māori kia noho ngākau pai tonu ai rātou me te mau mahara tonu ki te mana o tōu ingoa.’ Nā konei te Karauna i whakaae ai tērā, te taumaha o ngā mahi a ngā tūpuna o Ngāi Tahu, nā rēira i tū whakaiti atu ai i nāiane i mua i ā rātou mokopuna.
- E whakaae ana te Karauna ki tōna tino hēanga, tērā i takakino tāruaruatia e ia ngā kaupapa o te Tiriti o Waitangi i roto i āna hokonga mai i ngā whenua o Ngāi Tahu. Tēnā, ka whakaae anō te Karauna tērā i roto i ngā āhuatanga i takoto ki roto i ngā pukapuka ā-herenga whakaatu i aua hokonga mai, kāore te Karauna i whai whakaaro ki tāna hoa nā rāua rā i haina te Tiriti, kāore hoki ia i whai whakaaro ki te wehe ake i ētahi whenua hei whai oranga tinana, whai oranga ngākau rānei mō Ngāi Tahu.
- E whakaae ana te Karauna tērā, i roto i tāna takakino i te wāhanga tuarua o te Tiriti, kāore ia i whai whakaaro ki te manaaki, ki te tiaki rānei i ngā mauanga whenua a Ngāi Tahu me ngā tino taonga i hiahia a Ngāi Tahu ki te pupuri.
- E mōhio ana te Karauna tērā, kāore ia i whai whakaaro ki a Ngāi Tahu i runga i te ngākau pono o roto i ngā tikanga i pūtake mai i te mana o te Karauna. Nā tāua whakaaro kore a te Karauna i puaki mai ai tēnei pēpeha a Ngāi Tahu: “Te Hapa o Niu Tīreni”. E mōhio ana te Karauna i tāna hē ki te kaipono i ngā āhuatanga whai oranga mō Ngāi Tahu i noho pōhara noa ai te iwi ia whakatupuranga heke iho. Te whakatauāki i pūtake mai i aua āhuatanga: “Te mate o te iwi”.
- E whakaae ana te Karauna tērā, mai rāno te piri pono o Ngāi Tahu ki te Karauna me te kawa pono a te iwi i ā rātou kawenga i raro i te Tiriti o Waitangi, pērā anō tō rātou piri atu ki raro i te Hoko Whitu a Tū i ngā wā o ngā pakanga nunui o te ao. E tino mihi ana te Karauna ki a Ngāi Tahu mō tōna ngākau pono mō te koha hoki a te iwi o Ngāi Tahu ki te katoa o Aotearoa.
- E whakapuaki atu ana te Karauna ki te iwi whānui o Ngāi Tahu i te hōhonu o te āwhitu a te Karauna mō ngā mamaetanga, mō ngā whakawhiringa i pūtake mai nō roto i ngā takakino a te Karauna i takaongetia ai a Ngāi Tahu Whānui. Ewhakaae ana te Karauna tērā, aua mamaetanga me ngā whakawhiringa hoki i hua mai nō roto i ngā takakino a te Karauna, arā, kāore te Karauna i whai i ngā tohutohu a ngā pukapuka ā-herenga i tōna hokonga mai i ngā whenua o Ngāi Tahu, kāore hoki te Karauna i wehe ake kia rawaka he whenua mō te iwi, hei whakahaere mā rātou i ngā āhuatanga e whai oranga ai rātou, kāore hoki te Karauna i hanga i tētahi tikanga e maru motuhake ai te mana o Ngāi Tahu ki runga i ā rātou pounamu me ērā atu tāonga i hiahia te iwi ki te pupuri. Kore rawa te Karauna i aro ake ki ngā aurere a Ngāi Tahu.
- E whakapāha ana te Karauna ki a Ngāi Tahu mō tōna hēanga, tērā, kāore ia i whai whakaaro mō te rangatiratanga o Ngāi Tahu, ki te mana rānei o Ngāi Tahu ki runga i ōna whenua ā-rohe o Te Wai

Pounamu, nā rēira, i runga i ngā whakaritenga me ngā herenga a Te Tiriti o Waitangi, ka whakaae te Karauna ko Ngāi Tahu Whānui anō te tāngata whenua hei pupuri i te rangatiratanga o roto i ōna takiwā.

- E ai mō ngā iwi katoa o Aotearoa e hiahia ana te Karauna ki te whakamārie i ngā hara kua whākina ake nei—otirā, ērā e taea i nāiane i te mea kua āta tau ngā kōrero tūturu ki roto i te pukapuka ā-herenga whakaritenga i hainatia i te 21 o ngā rā o Whitu hei tīmatanga whai oranga i roto i te ao hōu o te mahinga tahi a te Karauna rāua ko Ngāi Tahu.

## **Section 6      Text in English**

The text of the apology in English is as follows:

- The Crown recognises the protracted labours of the Ngāi Tahu ancestors in pursuit of their claims for redress and compensation against the Crown for nearly 150 years, as alluded to in the Ngāi Tahu proverb ‘He mahi kai takata, he mahi kai hoaka’ (‘It is work that consumes people, as greenstone consumes sandstone’). The Ngāi Tahu understanding of the Crown’s responsibilities conveyed to Queen Victoria by Matiaha Tiramorehu in a petition in 1857, guided the Ngāi Tahu ancestors. Tiramorehu wrote:  
  
*“This was the command thy love laid upon these Governors ... that the law be made one, that the commandments be made one, that the nation be made one, that the white skin be made just equal with the dark skin, and to lay down the love of thy graciousness to the Māori that they dwell happily ... and remember the power of thy name.”*
- The Crown hereby acknowledges the work of the Ngāi Tahu ancestors and makes this apology to them and to their descendants.
- The Crown acknowledges that it acted unconscionably and in repeated breach of the principles of the Treaty of Waitangi in its dealings with Ngāi Tahu in the purchases of Ngāi Tahu land. The Crown further acknowledges that in relation to the deeds of purchase it has failed in most material respects to honour its obligations to Ngāi Tahu as its Treaty partner, while it also failed to set aside adequate lands for Ngāi Tahu’s use, and to provide adequate economic and social resources for Ngāi Tahu.
- The Crown acknowledges that, in breach of Article Two of the Treaty, it failed to preserve and protect Ngāi Tahu’s use and ownership of such of their land and valued possessions as they wished to retain.
- The Crown recognises that it has failed to act towards Ngāi Tahu reasonably and with the utmost good faith in a manner consistent with the honour of the Crown. That failure is referred to in the Ngāi Tahu saying ‘Te Hapa o Niu Tirenī!’ (‘The unfulfilled promise of New Zealand’). The Crown further recognises that its failure always to act in good faith deprived Ngāi Tahu of the opportunity to develop and kept the tribe for several generations in a state of poverty, a state referred to in the proverb ‘Te mate o te iwi’ (‘The malaise of the tribe’).
- The Crown recognises that Ngāi Tahu has been consistently loyal to the Crown, and that the tribe has honoured its obligations and responsibilities under the Treaty of Waitangi and duties as citizens of the nation, especially, but not exclusively, in their active service in all of the major conflicts up to the present time to which New Zealand has sent troops. The Crown pays tribute to Ngāi Tahu’s loyalty and to the contribution made by the tribe to the nation.
- The Crown expresses its profound regret and apologises unreservedly to all members of Ngāi Tahu Whānui for the suffering and hardship caused to Ngāi Tahu, and for the harmful effects which resulted

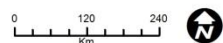
to the welfare, economy and development of Ngāi Tahu as a tribe. The Crown acknowledges that such suffering, hardship and harmful effects resulted from its failures to honour its obligations to Ngāi Tahu under the deeds of purchase whereby it acquired Ngāi Tahu lands, to set aside adequate lands for the tribe's use, to allow reasonable access to traditional sources of food, to protect Ngāi Tahu's rights to pounamu and such other valued possessions as the tribe wished to retain, or to remedy effectually Ngāi Tahu's grievances.

- The Crown apologises to Ngāi Tahu for its past failures to acknowledge Ngāi Tahu rangatiratanga and mana over the South Island lands within its boundaries, and, in fulfilment of its Treaty obligations, the Crown recognises Ngāi Tahu as the tangata whenua of, and as holding rangatiratanga within, the Takiwā of Ngāi Tahu Whānui.
- Accordingly, the Crown seeks on behalf of all New Zealanders to atone for these acknowledged injustices, so far as that is now possible, and, with the historical grievances finally settled as to matters set out in the Deed of Settlement signed on 21 November 1997, to begin the process of healing and to enter a new age of co-operation with Ngāi Tahu.”
- 
- APPENDIX Two: Ngāi Tahu Takiwā

- Ngāi Tahu Northern Boundary
- Coastal Marine Area to 12 miles
- Waters only from 12 to 200 miles



# Ngāi Tahu Claim Area Definition



Name	[redacted]
Organisation	IHC
Role	[redacted]
Interest group	People with intellectual disability and their families (consumers)
Publish response	You may publish this submission

10 October 2018

██████████  
 Acting Principal Policy Analyst  
 Senior advisor  
 Ethics  
 Quality Assurance and Safety  
 Protection, Regulation and Assurance  
 Ministry of Health  
 Wellington



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Dear ██████████

#### **Draft National Ethical Standards for Health and Disability Research**

IHC welcomes the opportunity to give feedback on the draft National Ethical Standards. Our comments in this letter are further to those made at the consultation discussion meeting organised by Ezekiel Robson on 17 September.

IHC strongly supports the Draft Standard's principles of Te Ara Tika, references to inequality and inequity, rejection of stereotypes and recognition of different population groups. We like the mention of the ethical principles and standards being applied not only to research but to other relevant areas of practice.

People with intellectual disability have some of the poorest health, social and economic outcomes of any population group in New Zealand. They experience inequities in access to and quality of healthcare and health promotion activities. Despite this they are often positioned as 'other' or too difficult to include and thus excluded from participating in and contributing to research. The Draft Standards provide a framework to increase the participation and contributions of people with intellectual disability in research.

To further help we suggest that what is meant by health and disability research is made clearer by distinguishing between

- Participating in general population research on health and wellbeing or as members of particular population groups such as Maori, Pacific, women, children, in a regional area.
- Participating in research about and with people with an intellectual disability such as on health or wellbeing for this population group.

Incorporating supported decision making (8.15) and supported consent (9.15) as has been done in the Draft Standards is a positive step in both aligning with New Zealand's obligations under the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) and giving practical ways to support and safeguard people's rights, consent and participation in research.

Other work to consider is

- The Health and Disability 2017 consultation on Right 7(4) of the Code of Health and Disability Services Consumers' Rights (informed consent to health and disability research) and their recommendations.

- Office of Disability Issues, Ministry of Social Development coordinated work with government and community and disability organisations on UNCRPD Article 12: Equal recognition before the law. Being able to exercise legal capacity and supports and safeguards for decision-making are central to this work.

Please do not hesitate to contact us if you if there anything further we can help with.

Yours sincerely



Director of Advocacy

Name	[redacted]
Organisation	AbbVie
Role	Regulatory Policy and Intelligence Analyst
Interest group	Commercial Sponsor
Publish response	You may publish this submission

*Proposed Regulation/Guidance Document:*

**Due Date for Comments to RPI: 27<sup>th</sup>  
September 2018**



Regulatory Policy & Intelligence  
Sharing Knowledge and Insight

### Specific Comments on the Text

Indicate text proposed for deletion with ~~strike through~~ and text proposed for addition with **bold and underlining**.

You must provide the information requested in each column of the table below. Comments lacking all information will not be included in RPI's comments to the Trade Association and/or the Health Authority.

Line Number	Current Text	Proposed Change	Rationale or Comment
	<ul style="list-style-type: none"> <li>Section 9.34               <ul style="list-style-type: none"> <li>Current text: "what costs will be reimbursed and how participation will be recognized"</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>The expectations of what the participant information sheet must state about "how participation will be recognised" needs to be clarified.</li> <li>New Zealand's July 2012 Ethical Guidelines for Intervention Studies uses the following wording: "payments or other forms of reimbursement, if any, provided in recognition of participation." This wording makes clearer that "recognition" means reimbursement</li> </ul>	<p>If recognition in the new Ethical Standards means reimbursement and other payments to study participants, it would be helpful to state more the point more clearly.</p>



Line Number	Current Text	Proposed Change	Rationale or Comment
		to study participants for the cost of participation in the study (for example, reimbursement of travel expenses).	
	<ul style="list-style-type: none"> <li>Section 9.34               <ul style="list-style-type: none"> <li>Current text: “the right of participants to access tissue and/or data about themselves collected as part of the study”</li> </ul> </li> </ul>	This “right of participants to access tissue” seems to overlap with and may even be inconsistent with the requirement stated later to tell study participants “whether they may be able to have leftover tissue samples returned to them.”	If these points are distinct, please clarify how they are different. If they are the same information that would be provided to study participants, please consolidate them into one point.
	<ul style="list-style-type: none"> <li>Section 9.34               <ul style="list-style-type: none"> <li>Current text: “if and how the research findings will be translated into health care”</li> </ul> </li> </ul>	This point seems to overlap with the point that follows it about letting the study participant know if the research will be commercialised. Commercialisation would translate the research findings into health care.	If these points are distinct, please clarify how they are different. If they are the same information that would be provided to study participants, please consolidate them into one point.
	<ul style="list-style-type: none"> <li>Section 9.34               <ul style="list-style-type: none"> <li>Current text: “information about how study data will be used and where it will be stored (including any specified or unspecified future use or uses)”</li> </ul> </li> </ul>		In today’s electronic world, trying to explain “where” data will be stored can become a long and technical explanation that may be difficult to understand. It is advised not to require this information in the PDCF, but rather simply tell study participants that the stored data will be secure.
	<ul style="list-style-type: none"> <li>Section 9.34               <ul style="list-style-type: none"> <li>Current text: “whether the research findings may be</li> </ul> </li> </ul>		This needs clarification. What ownership rights are participants expected to have in the findings?



Line Number	Current Text	Proposed Change	Rationale or Comment
	commercialised and any ownership rights participants may have over these”		
	<ul style="list-style-type: none"> <li>Section 9.34 <ul style="list-style-type: none"> <li>Current text: “the form in which the data will be accessed, used and stored during the life cycle of the research data (identifiable, re-identifiable, non-identifiable)”</li> </ul> </li> </ul>		These newly introduced terms/definitions are not in harmony with what other regulators such as the EMA, TGA and FDA have used.
	<ul style="list-style-type: none"> <li>Section 13.80</li> </ul>		The option is opt out of receiving results is better done/communicated at the end of participant’s participation in the study (their end of study participation and not study completion).
	<ul style="list-style-type: none"> <li>Section 14.36 <ul style="list-style-type: none"> <li>Current text: “These standards do not use the terms ‘de-identified’, ‘anonymous’ and ‘anonymised’ data because their meanings can be confusing”.</li> </ul> </li> </ul>	These newly introduced terms are not in harmony with other regions in the world and very likely continue to create confusion.	The EMA under Policy0070 uses “anonymized and deidentified” interchangeably. In these Standards, the definition of reidentifiable seems to equate “de-identified” and non-identifiable seems to equate with anonymized.

Response number	103
Name	[redacted]
Organisation	WelTec
Role	[redacted]
Interest group	Researchers / consumer
Publish response	You may publish this submission

## National Ethical Standards for Health and Disability Research: Consultation document

The Ethics and Research Committee of the Wellington Institute of Technology (WelTec) and Whitireia Community Polytechnic discussed this document at its recent meeting.

The Committee would like to take the opportunity to commend the National Ethics Advisory Committee for producing a document that will be a valuable resource and will provide us with greater guidance to our future decision-making as an Ethics Committee.

We welcome the increased clarity provided for the definitions of confidentiality, anonymity, vulnerability, and identifiability, together with the enhanced framework and responsibilities associated with data collection, use, storage, and longevity.

In addition, the document aligns well with the Code of Ethics and Code of Conduct for Social Work. However, we do suggest broadening 'health' to a definition that is more holistic to include the areas of counselling, social work, and youth development.

Once again, we commend the NEAC on a document that strengthens both health and disability research and which removes the prescriptiveness in the previous document thereby presenting a positive approach towards ethical standards.

