



Summary of Submissions

Consultation on the Draft National Ethics
Standards for Health and Disability Research

Summary of Submissions

Table of Contents

FOREWORD.....	2
BACKGROUND	3
CONSULTATION PROCESS	6
PUBLIC MEETING SUMMARIES	8
AUCKLAND	8
WAIKATO.....	9
WELLINGTON.....	11
CHRISTCHURCH.....	12
DUNEDIN.....	14
PROFILE OF SUBMISSIONS.....	16
ANALYSIS	17
CORE THEMES.....	17
FIT FOR PURPOSE	20
COVERAGE OF ETHICAL GUIDANCE.....	25
.....	25
SCOPE OF THE STANDARDS	28
ETHICAL PRINCIPLES.....	31
RESEARCH INVOLVING MĀORI.....	34
RESEARCH INVOLVING PACIFIC PEOPLES	36
CATEGORIES OF PARTICIPANTS	38
INFORMED CONSENT	41
RESEARCH BENEFITS AND HARMS	46
RESEARCH DEVELOPMENT AND DESIGN	48
TYPES OF STUDIES.....	50
RESEARCH CONDUCT.....	52
HEALTH DATA	54
DATA BANKS.....	58
HUMAN TISSUE	60
BIOBANKS	62
RESEARCH WITH STEM CELLS.....	64
COMPENSATION FOR COMMERCIALY SPONSORED INTERVENTION STUDIES.....	65

Foreword

NEAC is charged with setting the standards nationally for the ethical conduct of human participant research into health and disability. They apply to all health and disability research taking place in New Zealand.

Tika is the recognised basis for human participant research - improved understanding and health and disability outcomes, for people now and in the future. Hence, there is a strong ethical imperative to research, and a necessity to involve human participants in this research.

Strong well established national standards for this research aim to achieve two connected things. First, to provide protections for those who are asked to participate, and those who do participate, through manaakitanga (caring, nurturing), and respect, ensuring that their rights and well-being are central. Second, to reassure the New Zealand public, as potential participants in and potential beneficiaries of research that the research enterprise is trustworthy, and that it is worth investment and support.

This trust in the ethical integrity of the research enterprise is increasingly important. Ethical oversight and governance of research is an important contributor to this trust. The achievement of mana (equity) in health and disability outcomes for all communities in New Zealand requires the participation of all communities, and this in turn requires whakapapa – the generation of trusting relationships. The continual development of new research methods requires oversight of their ethical implications, as is the case with research using data and matters relating to privacy.

National ethical guidelines on health and disability research have been available since 2006 (for Observational Studies) and 2008 (for Intervention Studies). Though these two texts were slightly updated in 2012, the present iteration represents the first major reconsideration of the guidelines since their inception.

NEAC commends the work of the Guidelines Working Party, and to all of those who have been involved in the drafting of the Standards. NEAC is committed to working with all of those in the sector – from consumers to researchers and government agencies and commercial stakeholders, to ensure advice and standards are relevant and workable.

NEAC decided that in order to continue with completion of the NEAC Standards for Health and Disability Research, two major ethical gaps that required more considered thought would be flagged for future projects. These were quality improvement ethics and related activities, and emergency ethics / pandemic ethics. This is in line with the Standards being a living, flexible document.

The responses from the consultation have created four streams of work: structural changes to existing content and review of language, the integration of uncontroversial changes and improvements made by submitters, new content generation, and issuing advice based on high level feedback (beyond the scope of the standards).

NEAC want to thank everyone that submitted feedback to this important national document, and to all of those who attended the public meetings and gave their views. NEAC have received extensive feedback and have a clear line of sight for how to make this document a relevant and high value document for years to come. NEAC aim to complete the Standards by the end of July 2019.



Dr Neil Pickering

Acting Chairperson

Background

The National Ethics Advisory Committee

The National Ethics Advisory Committee (NEAC) is a committee set up under New Zealand legislation to advise the Minister of Health on ethical issues in health services and research, and determine national ethical standards for the health sector. NEAC has up to 12 members that are appointed by the Minister of Health. Members bring expertise in ethics, health and disability research, health service provision and leadership, public health, epidemiology, law, Māori health and consumer advocacy.

The Committee was set up in 2001. Its full name is the National Advisory Committee on Health and Disability Support Services Ethics, and it is also known by its Māori name; Kāhui Matatika o te Motu, which translates as 'National Ethics Group'. NEAC acts as an independent advisor to the Minister of Health. It has provided advice to the Minister on a range of issues, including on the system of ethical review of research and on the conduct of clinical trials in New Zealand, and ethical issues in elective health care services (view Ethical issues in elective services: NEAC report to the Minister of Health).

The Ministry of Health provides policy staff and other resources to support NEAC but the Committee remains independent of the Ministry and its work.

NEAC Members

- | | |
|---|---|
| Neil Pickering: Health Research Council nominee | Kahu McClintock: Māori member, Kaupapa Māori researcher |
| Maureen Holdaway: Health researcher | Liz Richards: Community/consumer |
| Julian Crane: Health researcher | Hope Tupara: Health professional |
| Adriana Gunder: Community/Consumer | Dana Wensley: Lawyer |
| Wayne Miles: Health professional | |

Prior members of NEAC

Monique Jonas

Martin Wilkinson.

Reviewing the ethical guidelines

NEAC issues guidelines that set out the ethical standards that must be met by researchers when they undertake health and disability research. These guidelines are also used by ethics committees that review research study proposals – they are responsible for checking that each study meets the ethical standards set out in NEAC's guidelines.

These ethics committees include those run by universities and the four statutory health and disability ethics committees that must follow the procedural rules (ethics.health.govt.nz) issued by the Ministry of Health. Unlike these ethics committees, NEAC does not have a role in considering or approving individual

proposals for research.

In 2015 NEAC committed to review the 2012 [Ethical Guidelines for Intervention Studies](#) and [Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities](#). NEAC commenced work on the revision in 2015. NEAC produced a draft zero version of the document. In 2017 the Ministry of Health set up a Working Group to develop NEACs draft to a final draft. The Working Group completed a draft document that was presented to NEAC. NEAC reviewed the draft and following a final revision, a draft document was presented to the public for consultation. This work aligns with the [Health Research Strategy 2017](#), which addresses investment and strengthening health research in New Zealand, particularly focusing on reducing inequity and improving health outcomes. The ethical standards are also a part of a general strengthening of the regulatory environment for health research.

Working Party

Role

The Working Party is a temporary group, set up by the Ministry of Health to:

- review the existing draft *Ethical Guidelines for Health and Disability Research* developed by the National Ethics Advisory Committee (NEAC)
- ensure that Māori ethical perspectives underpin all parts of the *Guidelines*
- take into account the broader policy environment, including ensuring that the draft is aligned to and informed by the following national and international developments:
 - the Therapeutic Products and Medicines Bill currently being drafted
 - thinking underpinning the Bill drafting on ACC compensation issues
 - reviewed with the United States' Federal Drug Agency standards, including implementation in 2018 of changes to the Federal Policy for the Protection of Human Subjects (known as The Common Rule)
 - updated requirements for the conduct of clinical trials in the European Union as contained in the Good Clinical Practice guidelines
 - other international developments in best practice ethical standards for health and disability research.

Membership

Membership of the Working Party will comprise a core group of eight to ten people who possess the following areas of expertise:

- health researcher with knowledge of intervention studies
- health researcher with knowledge of observational studies
- a person with knowledge of the concept of vulnerability in research
- a person with disability perspectives
- a Māori ethics specialist
- an international ethics specialist
- a tissue research and genomics specialist
- a big data / privacy / health information specialist

- a bioethicist
- a person with medico-legal knowledge.

Wherever possible, members will be people who can contribute in more than one of the above roles.

If expertise is needed outside of the core group, the Working Party will work with the Ministry Strategy and Policy team to identify sources of such expertise and invite them to comment and/or contribute.

Working Party Members

Karen Bartholomew

Wayne Miles

Kate O'Connor

Lorraine Neave

Devonie Eglinton

Neil Pickering

Maui Hudson

Barry Smith

Nora Lynch

Hilary Stace

Rochelle Style

Consultation Process

On 24 July 2018 the National Ethics Advisory Committee (NEAC) called for public submissions on the *Draft National Ethical Standards for Health and Disability Research: Consultation document 2018*.

*He waka eke noa
A canoe which we are all in with no exception*

Dissemination

The consultation document was available on-line at the Ministry of Health website and the National Ethics Advisory Committee website. The document was tweeted by the Ministry of Health. The document was emailed to a list of 3942 email addresses, comprised of researchers, research organisations, government agencies, patient and consumer interest groups and national and institutional ethics committees. The email list was generated by combining the Health and Disability Ethics Committee database of researchers, a targeted list of individuals and agencies developed by NEAC, the consultation list from the Health Research Strategy public consultation and a list of contacts for institutional ethics committees and district health board research offices.

The consultation was publicised in the Health Research Council publication 'HRC Update', the Health Precinct Advisory Council Christchurch newsletter, New Zealanders for Health Research Health Research Matters bulletin and the Otago Public Health mailing list.

Consultation Design

The focus of the consultation document was:

- Whether the Standards are fit for purpose: are the contents of the Standards helpful, clear, relevant and workable?
- Whether the Standards covers all relevant ethical issues: are there matters missing which on topics where ethical guidance should be provided? Are there any conflicts with other standards, laws or current pieces of work that should be considered?
- General feedback: should any paragraphs be amended? Are there terms that are confusing or could be better defined?

NEAC was aware of the complexity of ethical issues surrounding health and disability research. Therefore the consultation document provided the opportunity to provide detailed feedback on specific areas (chapters) of the draft standards. Submitters were welcome to provide as much or little feedback as they wanted, outside of answering a set of high level questions about the document as a whole.

The consultation was designed using Citizen Space, an online consultation tool. The consultation was sectioned into two parts.

The first part of the consultation is about the Standards (document) as a whole, and asks questions about being fit for purpose, the new structure, the scope of the standards and whether they are complete (gap analyses). **These questions were required to be completed in order to submit a submission.**

The second part of the consultation asks questions about each individual section or chapter of the Standards. Commenting on chapters was **optional**. Each section or chapter had a set of standard questions, as well as some particular questions relevant to that chapter, to help NEAC consider key issues,

Public Meetings

NEAC advertised five public consultation meetings and invited those interested in health research to in-person consultation meetings to support the public consultation of the National Ethics Advisory Committee's National Ethics Standards for Health and Disability Research.

- Auckland – Monday 3 September - Grafton Campus of the University of Auckland: Medical and Health Sciences Building
- Waikato – Wednesday 5 September - Upstairs Lounge, Gallagher Academy of Performing Arts - Te Whare Tapere
- Wellington – Friday 7 September - Horne Lecture Theatre, Capital & Coast District Health Board
- Christchurch – Monday 10 September - Manawa Building
- Dunedin – Wednesday 12 September - Hutton Theatre in the Otago Museum

The first half of the day was conducted as a presentation, explaining how the new sections of the draft Standards were developed, who was involved and providing an overview of new sections. Groups then broke out in different round table sessions to apply the draft Standards to case studies that helped foster discussion about the standards, and give their feedback on the standards.

Consultation Meetings

The NEAC Secretariat also held targeted meetings with stakeholders including the Ministry of Social Development, Oranga Tamariki, the Health and Safety Managers from the Health Safety Quality Commission Meeting and a group of disabled people as researchers and participants, who discussed issues of rights, access and inclusion.

Public Meeting Agenda

- Introduction and welcomes
10:00am – 10:15am
- Overview of the Standards
10:15am – 11:15am
- Open feedback 11:15am-
11:45pm

Topic 1: Fit For Purpose

Topic 2: Scope of the Document

Topic 3: Merging the Guidelines

- lunch 11:45-12:30pm
- Round table groups
12:30pm-1:15pm

Research with Māori, Pacific Peoples and Participants

Informed Consent

Benefits and Harms, Research Conduct

Research Development, Design, Types of Studies and Compensation

Data / Tissue / Biobanking

- Summary – feedback from groups 1:15-2:00
- Final thoughts 2:00pm-2:30pm

Public Meeting Summaries

Three hundred and forty-five participants in total registered to attend across the five public consultation meetings. Two members of the NEAC Secretariat recorded notes from the day that are included in the analyses.

Auckland

Feedback to presentation

Many people were complimentary of the proposed update, particularly in the assimilation of two documents into one. Both the complexity of the system and the wider ethics landscape itself were still seen as in need of improvement, but it was acknowledged that these guidelines were a good step forward.

The most common criticism present was the lack of reference to 'Good Clinical Practice' in the standards. One person objected to Māori consultation at the outset of research being obligatory, as this has the potential to compromise its outcome. There were also complaints about the restrictive nature of New Zealand law on research. A request was therefore made that NEAC request legal advice that could then be standardised and shared with researchers nationwide.

Summary of comments from focus groups

Research with Māori, Pacific peoples, and categories of participants

Much of the feedback drew attention to a conflict between scientific and Māori values. Specifically, there is a mistrust of authority, especially when there is a lack of transparency and honesty.

Some participants suggested that Māori be consulted throughout the stages of research, to ensure it is consistent with tika. This would prevent investigators from alienating Māori. To this end, it was proposed that the consultation process be improved, perhaps featuring a group of relevant people rather than a single expert. However, one member commented that Māori continuous involvement be optional, as this may compromise the research agenda. This linked to a comment that, ultimately, there must be an understanding between tika and scientific merit; for example, Māori to be re-consulted or re-consented when culturally sensitive issues arise in the course of research. The principle of self-determination was seen as of particular importance.

Concerning the screening and recruitment of Māori and other non-Europeans, some suggested that researchers liaise with specialised staff within the Ministry of Health, or with discipline-specific people (i.e. through universities). People were generally in favour of designing research to facilitate on-going dialogue between researchers and participants from these sub-groups.

Informed consent

Contextual problems were raised on the topic of securing informed consent from children. There was a practical concern about inducing anxiety in children during research, and that there is a problem in children knowing that any information provided will be made available to their parents as well. This could lead to a lack of honesty in under-age participants. In terms of securing consent, people wanted to clarify that this is not an event, but a process. Different documents and means of communication could be made available to children, and the researchers might consider categorising children based on their developmental stage

rather than age. It was said that the guidelines would also do well to reference the Health Information Privacy Code.

More general criticism tended to focus on the definition of patients' 'best interests.' Namely, how is this best determined? It is essential to conduct research on people unable to consent, and often the family are not the appropriate decision-makers.

One comment was made that bio-banking should never be mandatory. Some researchers noted that use is sometimes made of a distinct bio-banking consent form, and this should be adopted by the guidelines as a gold ethical standard.

Benefits, harms, and research conduct

One member found the chapters very helpful here, and others thought there could be better defining of terms 'researcher' and 'sponsor' in the guidelines. The shared opinion was that primary responsibility for proper research conduct rests with the chief investigator, and that there should be appropriate training and accreditation of researchers, particularly in relation to the cultural impact of their work. Priorities for members also included flexibility in who can provide peer review, transparency in data, and getting the process of ongoing consent right.

Research development and design, type of studies, and compensation

It was thought that implementing the standards would be difficult. Additionally, people reported a lack of clarity around the threshold for ethics review and the protocol requirements for low-risk observational studies. It was suggested as well that the qualifier 'human' be added to the document.

Data, tissue, and bio-banking

A theme emerging from the feedback was the importance of communicating the use of data with patients both during and post-research. People reasonably expect their data to be used only if potentially beneficial and de-identified, and for Māori this constitutes tika. One person requested that the standards for individual data be elevated to the same level of those in the use of tissue, and another thought the risks of data reconstruction be made clearer. However, one person praised the data governance plan laid out in the guidelines, and thought that the level of detail will be of great help at the institutional level.

Feedback on tissue and bio-banking was less polarised. Both the detail of tissue-use in study protocols and bio-banking governance in general were considered in of need work. A grace period was thought likely to be required.

Waikato

Feedback to presentation

Some questions were raised while acknowledging and complimenting the scale of work being done on the guidelines. The positioning of research in line with the national Health Research Strategy was brought up, as was how the NEAC Secretariat is analysing submissions on the draft document from both the public and private sectors.

The lack of clarity around HDEC scope of review in relation to audits and low-risk observational studies was a common criticism, as researchers found themselves submitting Scope of Review Forms as default practice. The ethical review process in general was seen as time-consuming and complex, and aimed primarily at clinical trials. There was a request for a forum to be held where all stakeholders could discuss

HDEC guidelines and operating procedures, and that the establishment of a distinct data ethics committee be considered.

Summary of comments from focus groups

Research with Māori, Pacific peoples, and categories of participants

While the draft was considered an improvement to the 2012 guidelines, many people made clear that there remain issues with collecting ethnic data. Large clinical trials are typically not developed in New Zealand and they subsequently have difficulty with consultation, and often this feels like a box tick exercise. This is significant as Māori and Pacific Islanders are invested in their cultures and need to know whether or not research will be nationally relevant. The guidelines' section on the best practice of ethnic data collection drew attention as well. Ethnicity is best thought of as fluid: people can identify with multiple ethnicities. It was said that there is an option to work with Stats NZ around guidance on the collection of ethnic data. It was warned, however, that breaking research data down in terms ethnic sub-groups was potentially meaningless given the small number of participants, and its subject matter may not be necessarily relevant to Māori in the first instance.

Some members brought up communication problems within the document. From the perspective of Pacific people, the standards could further consult them regarding the use of some terminology (for example, 'mala'). Additionally, there is a layperson understanding that research, when focused on a specific ailment, will have its findings disseminated for everyone's benefit rather than simply published academically. Parts of the standards also seemed aspirational, rather than focusing on research happening now.

Informed consent guidance

There was much positivity on this topic, both in terms of ease for researchers and in a more nuanced, less systematic, understanding of vulnerability. A main theme of concern however was the complexity of securing informed consent, and the risk of compromising a study when too much information is given out. The deaf community was cited as in particular need of clear and direct communication to ensure it is *their* consent which is being attained, not an intermediary's. The use of accredited translators would solve this problem.

Access to clinical trials was seen as an obstacle in this area by a number of people. On the side of the researchers, it is difficult to recruit patients into trials when one is also the clinician. On the side of the patients (children with rare disabilities and those invested in Stem Cell research were the examples given), the lack of equitable access to research forces many overseas.

Data

The new standards reportedly provide guidance on the management of patient databanks and registries in an ethics environment where this is needed, and researchers should be required to say what data and tissue will be used for at time of collection. Specific commentary is still needed in the standards on "front door consent," whereby localities have a 'front desk clause' which implies consent to data being used for audit activities.

Compensation

It was thought that the standards should comment on ACC equivalent cover in clinical trials, but generally it was not their place to address compensation and ACC pay issues.

CI and research conduct

When the issue at hand is informed consent the group felt that nurses should be given adequate training to secure this, as this would eliminate pressure on patients in declining requests from doctors or senior research staff.

Technical remarks on document

The methods used in updating the guidelines were approved of, as was the access to hyperlinks within the document. Still desired was a solid index and the closer linking of the standards with application forms.

Wellington

Feedback to presentation

Consultation participants in Wellington were generally positive about the draft guidelines and complimentary about conjoining the two current guideline documents.

During the consultation meeting a number of audience members noted that there is a perceived tension between NEAC's proposed guidelines and the law. Also, gaps were reported in the compensation section; namely, on the topic of ACC coverage for patients involved in commercial trials. Bureaucratic barriers to innovation were also highlighted, as were constraints on small studies lacking in research collaboration. One person commented that previous unfortunate experiments have raised awareness of the need for ethical research, and since the current system cannot provide oversight of every scenario it is reasonable that local ethics committees are more involved.

The lack of focus on disability research in the draft standards were raised and concern was expressed that it appeared that the words 'and disability' had been added in without consideration of what this research is. It was suggested that it is important not to just see disabled people as participants but to involve them in co-design of research and for the disability community to be more involved in research prioritisation and design.

The need to reciprocate public trust with greater governance over data collection was also highlighted.

Summary of comments from focus groups

Māori, Pacific peoples, and categories of participants

Confusion and lack of clarity around cultural consultation was a strong theme. It was not clear to people what constitutes cultural rigor, and even what could be defined as a 'consultation'. For example, was a group required for consultation? Did an individual suffice?

People indicated that there were institutional problems with consultation with ethnic communities. Beyond HDECs and universities it was not clear to researchers who to approach. The guidelines were silent on independent agencies, and the lack of a cultural network became apparent. A warning was given that there is a risk of overburdening the experts who are currently utilised for consultation. Additionally, the place of consultation within the process of research drew some attention, as too often it becomes a box ticking exercise. Trust with ethnic groups could be nurtured by consulting them throughout the research continuum.

On a structural level, the draft was commended for acknowledging the cultural, and therefore ethical, differences between Māori and Pacific peoples, and for successfully aligning with Te Ara Tika (though it was suggested that Te Mata Ira be taken into greater account). However, it was noted that there was some duplication between the Māori and Pacific material, and it might be useful to state any general principles at the outset.

The inherent risk of storage of ethnicity data was raised and it was identified that a duty of care must be maintained in this data's collection.

Informed consent

Many people commented that the guidelines' tone seemed paternalistic. The "need to protect children" stated in section 8.36 was given as an example, and the use of the word "should" was also mentioned. Parental consent was another point of concern. One person was unsure about the age of consent quoted in section 8.28 as "16 years", and attendees also thought that obtaining parental consent for Māori and Pacific children may be more complicated than indicated in the document. An attendee advised that there are practical issues with withdrawing data if the participant later requests this when turning of age, and we should not be promising things we cannot action.

It was noted that the vulnerability of the researchers, such as compassion fatigue, also needs to be taken into account and currently the document lacks guidance about this.

It was pointed out that there is a lack of guidance on types of circumstantial consent, such as electronic and emergency consent. Additionally, emphasis was placed by one attendee that ethics committees are not responsible for the law, and the document will need to be aligned with the HDC guidelines as a result, for example to clear up uncertainty about patient 'best interest'.

Research design and development

Those attending agreed that this area was well covered in the draft document.

Data, tissue, and bio-banking

One session participant was very pleased with document's coverage of registries and data transfer overseas. The major concern with both is ensuring that interested parties honour their initial commitments. It was said that the guidelines must also try to future-proof against emerging practices such as the commercialisation of tissue banks, AI development, and predictive analysis.

The use of Official Information Act (OIA) requests to gather data for research was an additional theme of discussion. People were of the opinion that the releasing of data under an OIA request needs to be related to the purpose for which it was collected.

Christchurch

Feedback from presentation

Those attending the Christchurch consultation meeting placed high value on the use of common language in ethical guidelines, so that they might be applicable for researchers involved in international trials. It was suggested that this language be as accessible as possible, so as not to dissuade non-health researchers from running innovative studies. Many of those attending expressed a desire for commonality in language and approach to bring both consistency in the decision-making process across HDECs and an alignment of DHB research with the NZ Health Research Strategy.

It was also mentioned that the guidelines should leave room for contextual factors in research. The case of pregnant women being categorically excluded from health research was cited, and this practice raises questions of gender equity. It was suggested that exclusion decisions therefore be context-sensitive rather than systematic. Additionally, one attendee was strongly opposed to the requirement to seek legal advice on research undertaken on incompetent patients, and thought that the guidelines should provide the framework for assessing the appropriateness of a study.

A comment was made that the risk of not undertaking a piece of research should be stated in ethics applications, and the standards should acknowledge potential harm to patients due to the barriers to undertaking a research project.

Questions and comments also focused on the guidelines' stance on medical devices, the legality of sourcing international bio-bank data, whether the scope of the HDEC should be reviewed, and NEAC's position on the use of European data standards as an international baseline.

Summary of comments from focus groups

Research with Māori, Pacific peoples and participants

Those attending the consultation expressed a number of concerns at researchers' current capacity for consultation with Māori. The capacity to consult varies across New Zealand, those consulted are often expected to provide this service on their own time, and there is a risk that local communities (Māori, Pacific, and other) can become over-consulted. Researchers who are not supported by a university or DHB often struggle to set up a consultation process. Also, consultation tends to happen towards the end of the application processes which creates the danger of cultural approval becoming a box tick or afterthought.

Suggested solutions to some of the above issues included: establishing reciprocity with participants and those being consulted with; and establishing of a 'consultation group' which is generally available to researchers and the health sector.

Informed consent

Many attendees commented on the lack of standardised guidelines on informed consent. At present researchers are forced to seek independent legal advice. Often this advice can be inconsistent, including with that received by HDECs. It was suggested that NEAC request a legal opinion and develop a framework for researchers to use when working with patients who cannot provide consent. It was also noted that patient information sheets are overly complex due to a need to satisfy lawyers. A separation of consent forms from information sheets would also be helpful. Complexity around informed consent is tending to deter researchers.

Another theme in the discussion was the conflation between ethical and publication requirements. HDEC review is often required in order to publish the research that is outside the scope of HDEC review. It was suggested that an additional document be developed that would satisfy publishers.

Research development

Some attendees expressed concern that there are big risks associated with study data and there will be greater risks associated with it in future. This includes cases where large companies have sought to buy DHB data. It was also noted that there is a lack of adequate follow-up on research projects to ensure studies are being carried out as proposed. The comment was made that categorization of research is very broad and it would be better to classify research according to degree of risk than by subject-matter. Problems with ACC compensation to research participants was also mentioned.

Data, tissue, and bio-banking

Attendees considered that there needs to be clearer governance arrangements around bio-banking. More collaboration between bio-banks was also desired. DHBs hold a lot of data which external researchers often want to make use of, and guidance is needed on this. One consultation participant highlighted that data has a clear lifecycle, and there will need to be sufficient resources to close data banks when the appropriate point is reached.

One attendee was pleased that the standards differentiate between a study on specific material held in a bio-bank and incidental findings. Another consultation participant thought a differentiation could be made between studies exclusively using bio-bank data and those with a bio-banking component. Further, there was uncertainty about the place and ownership of biometric data, such as in the use of vocal and facial recognition software. It was noted that bio-banks will need to be well resourced to achieve their aims in the current absence of adequate funding. Advice was also sought on balancing tissue collection with a need not to overwhelm patients (eg, when retesting following significant clinical findings).

Specific comments on the draft guidelines included: providing more detail on Microbiomes; reworking section 15.13 (stating the professional requirements for the collection, use, and storage of tissue) and potentially linking it to the SOPs; and the definition in footnote 40 differs slightly from that in the Human Tissues Act 2008.

Dunedin

Feedback from presentation

Many audience members were impressed by the document and commented on its readability. Its subject-matter was thought to adequately capture and communicate issues arising in research. One person commended the bio-banking section in particular.

However, a number of questions and requests for clarification arose in the process. One member asked whether an expert on commercialisation and device innovation was involved in the development of the draft. The place of research dealing with legally risky subjects (for example, drug-taking communities) under the new guidelines was also queried. There was further questioning of whether these standards were balanced with the Education Act in regards to academic freedom, and if they covered the establishment of health registries. A specific request for clarification of section 8.35 was also made in regards to the definition of 'undue influence.'

Of the direct criticism offered a central theme was a perceived vagueness around non-consensual research. It was commented that there is a current tension between the ethics process and the rights of people with intellectual disabilities, and there is a need to acknowledge that research may be of benefit to them. There should also be more specific focus on supporting these individuals, for example in making documentation accessible, and ensuring autonomy and dignity while research is conducted. The issue of consent arose in two additional areas. One audience member suggested that better guidance around the assent of children was needed, particularly in terms of age requirements. Another raised the subject of unconsented use of tissue, where ethics committees ought to better weigh the public good of this research against the autonomy of patients. This was salient to another suggestion that tissue be automatically moved to bio-banks rather than destroyed.

Much feedback also concentrated on the need for guidance on datasets. Many journals now require datasets as part of the publication process, and guidelines must manage privacy risks while not hindering the publication of results. One such risk to focus on is the sending of data overseas where control is lost, bringing the danger of manipulation. It was thought that any subsequent development of the standards will need to consult any nationally significant databases and bio-banks.

Isolated comments referenced a greater need for consistency across HDECs, the overly demanding quantity of documentation required for commercial research, and the need for ethical guidelines to offer guidance on the use of cadavers in research and training.

Summary of comments from focus groups

Māori, Pacific peoples, and participants

The central message from this session was the importance but also complication of collecting data from minority ethnic groups. There was confusion about who to contact for Māori consultation when conducting national projects, and how consent is to be managed for long-term research. A proposed solution was the development of a network to better put researchers in touch with Māori.

Informed consent

A problem with the wording of informed consent was raised: it needs to be neutral so as not to imply a disadvantage to patients who cannot provide it. Provision should also be made in the guidelines regarding the readability of information sheets; patients must understand what is going to happen, not just be told. The question of how far informed consent applies to the future use of databases was also put forward.

Benefits, harms, conduct, development and design

Feedback was favourable towards the added material around research development and study design, as flexibility is welcome in this area. However, people noted that the royal society should be referenced on research conduct, and that any acknowledgment of care for the researcher ('burn out' for example) is missing from the guidelines. Additionally, compensation for participants was said to be appropriate both for participation in, and harm occurring in, the research process.

Data, tissue, and bio-banking

There were a number of concerns about privacy and consent. As journals require data to be submitted, it was thought that a small sample size in a small country brought the danger of participants being identified even with data de-identification. The problem of data use beyond the original research project was voiced as well due to the difficulty of keeping track of it. Further, HDECs were not seen to have the expertise to adjudicate on issues of tissue and consent in seroprevalence studies. As a purely pragmatic point, the general benefits of bio-banking were said to be offset by its resource-intensiveness, and this leads to a question of who is to finance them.

Profile of Submissions

Types of Submission

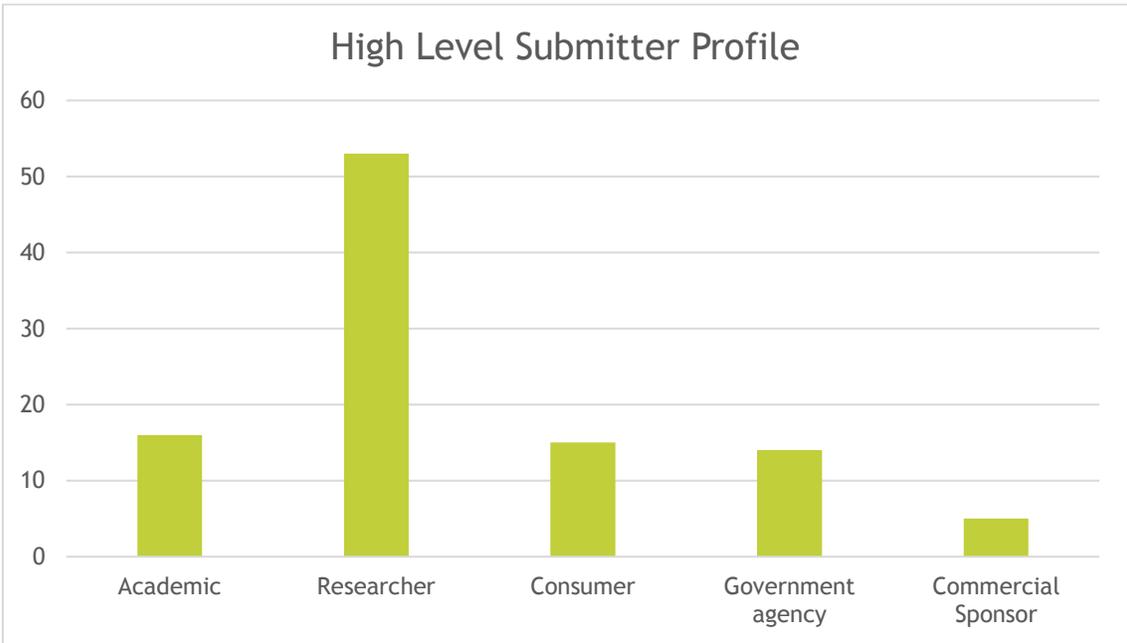
A total of 103 submissions were received. NEAC requested submitters to use the online tool Citizen Space. However, in order to ensure all stakeholders could provide feedback, offline submissions were accepted.

72 Submissions used the Citizen Space online consultation tool. All 72 submitters completed the first part of the consultation, as it was mandatory. The chapter feedback was optional, and a summary of how many Citizen Space participants commented on that section is provided in the introduction for each section.

31 submissions were received by email or post. Only 2 of the 31 submissions received by email or post used the consultation format provided by NEAC. An important point is that 29 submissions did not participate in the Likert scales, or follow the structure of the majority of submitters. To ensure feedback was heard, the 29 submissions were manually integrated into the high level analyses and any feedback on particular chapters or paragraphs were incorporated.

Categories of Respondent

The categories of respondent are set out below, with the numbers of submissions received from each group. 'Researcher' includes those primarily involved in research, such as research offices. Submitters were only able to select one categories, where they often belonged to multiple.



Analysis

Preamble

Feedback from the consultation was rich in detail and involved varying degrees of feedback, ranging from high level feedback about the wider ethics sector to detailed suggestions of changes or clarifications for particular paragraphs.

The NEAC Secretariat provided NEAC with a number of reports from the data that enabled them to view it in different ways, including a full list of submissions ordered by submitter, a dataset that was organized by question and filtered by positive, neutral, negative feedback, and lastly a high level overview of themes and areas for development.

This document contains an overview, and high level summary, of the feedback received through all avenues of consultation. This document aims to give the reader insight into the range of issues and views which arose during the consultation on the first draft of the new standards. It doesn't attempt to evaluate them, nor to indicate how they may be responded to. As a result, the reader may well find that the views represented are sometimes in tension or even conflict with one another. Some of the views represented might not gain much support from readers or other submitters.

For those who submitted feedback using Citizen Space, Likert scales were completed to give an indication of how submitters felt about the standards and set some context for assessing the feedback.

This report contains feedback from online submissions, offline submissions, and incorporates feedback from the public consultation meetings.

Some feedback goes beyond the scope of the standards. However, the standards do not sit in isolation, so this feedback is important when considering the implementation of the standards, and the wider ethics and research landscape. NEAC has a role in providing advice for the health and disability sector as a whole, and appreciates the thoughtful and considered feedback.

Core themes

Inclusion, representation and fairness of advancement of knowledge

An overarching theme was advancement of knowledge, and how fairness, inclusion, and representation among different patient groups and types of participants were considered in the Standards.

The focus and consideration of Māori views was highly commended. There are changes and improvements to be made but overall the feedback relating to recognising the importance of research with Māori was positive and supportive. The inclusion of Māori principles embedded throughout the document was also well received. However, the extent to which they are integrated in various chapters was recognised to differ. NEAC will work on this through further engagement with Māori.

Another area this theme came through was with respect to disability perspectives, and the differences between health research and disability research. There was a need for more information on disability from a strategic and representative point of view. Conflation between health and disability, the need for an equity focus, responsiveness, and access came through a number of submissions, and will be followed up with more engagement and redrafting.

LGBTBIQ+ populations also require more consideration, in terms of data collection and equity.

Lastly, there was a general concern about the impact of New Zealand law on access to research, particularly for participants who cannot provide their own consent, but also with regards some research designs such as cluster control studies.

Safeguards, wider ethics landscape and impact of the Standards

Another theme related to high level concerns or feedback about the wider New Zealand ethics landscape. These themes and issues are largely outside of the scope of the draft Standards – however NEAC has consulted on these issues in their cross-sectorial ethics work in the past, and will follow up this work and will write to the relevant agencies in order to explore how to resolve some of these issues.

ACC exclusions for commercially sponsored clinical trials was a common concern. NEAC put up advice to the Associated Minister of Health, Hon Minister Dunne, in 2015 (<https://neac.health.govt.nz/publications-and-resources/advice-minister-health-0/neac-advice-compensation-treatment-injury-0>). NEAC will review their advice in light of any changes since 2015, and will write to the Minister of Health Hon Dr David Clark with advice, taking into account feedback from the public consultation.

There were a few requests for guidance on ethics review processes in New Zealand. Many other countries' ethical standards documents explain when ethics review is required, and what an ethics committee must be comprised of, in their national standards. NEAC will consider whether it is possible to include more guidance for new researchers in the standards in the final draft. Related to this request was feedback about Māori consultation, locality review, and information for researchers on how to meet these requirements. NEAC takes the view that the Ethics Standards should not be overly prescriptive, but acknowledged that more information can be provided on the New Zealand ethics landscape.

A further consideration was the scope of the standards: more information on observational research (qualitative, ethnographic, etc.) was requested. A few submitters took the view that the standards were weighted towards clinical or biomedical research. This will be considered when revising the document, including seeking expert advice if required.

NEAC discussed the scope of the standards, noting this was a very common and complex theme. NEAC decided that the scope ought to remain broad – as health and disability research is a broad concept - but this broadness could be tempered by having clear guidance on risk and how risk may relate to oversight. This was to temper concerns from the sector around the practical impact of the Standards. NEAC's view is that the guiding principles are relevant whether or not ethics review is required, and the interpretation of those principles should be commensurate to risk. A section on ethics review in New Zealand is to be drafted, to link with the new categories of risk.

Accessibility, complexity and functionality of the Standards

NEAC observed that one of the most common themes related to structure and functionality of the document. Clarification and review for relationship between Standards, commentary, and introductions came through many submissions. NEAC have discussed and agreed upon a plan to restructure the document that should address the concerns raised in the feedback.

NEAC read with interest the feedback about the interplay with the law and ethics, in particular with areas of right 7(4), cluster control trials, and community intervention studies. A submitter suggested that the writers of the Standards should be careful about stating what is permissible within New Zealand law. NEAC met and discussed this tension, and noted that the Standards will be developed as ethical guidelines and should leave the determination of the law to legal experts. Instead of stating what is legal in New Zealand, the Standards will provide relevant references or links (for instance, to the "legal requirements" section) and state that legal advice should be sought where appropriate.

NEAC directed the Secretariat to develop one section on ethics and the law, following the format of the Australian National Standard, whereby the tension between ethics and the law is set out clearly, and a

substantive list of regulation, legislation and law is set out for researchers to be aware of. In a few key areas, it should be noted or flagged where there is legal ambiguity, but there should be no areas where the Standards make determinations on what is or is not legal in New Zealand. NEAC note that this is a shift from the draft Standards approach.

This decision was based on the views that the law was often not written for research, that there are certainly cases in New Zealand where something is ethical but unclear in terms of legality. There are also differing opinions with respect to these grey areas.

Balancing protections with facilitating knowledge advancement

Balance as a theme was observed throughout the document, in terms of balancing principles, balancing information, and balancing protections. There was feedback on informed consent – in particular in relation to reconsidering the structure of managing information through the informed consent process, and how to balance informed requirements against information overload.

In relation to this was a wider challenge, how can the standards better explain proportionality? For example, lower risk research not needing as much oversight and or complexity in meeting standards as high risk research.

“We appreciate the consideration of vulnerability as intersecting with other needs or experiences and wish to further reinforce that perceived vulnerability may in fact underline the importance of hearing the perspective of a particular group. The standards state that special consideration and protections must be given to these groups. It is important that the interpretation of this is not taken in a way that ‘others’ them or dissuades interaction, that implies they don’t know their own needs or that a paternalistic approach should be taken. It may be better to look at ensuring “appropriate” considerations are taken. We note that this is the section where confusion over Social Model understanding of Disability occurs.”

This challenge will be taken up by NEAC when redrafting the Standards, with one suggestion being to develop different levels of risk in the benefit and harm chapter, and use this to identify proportionality to reflect risk-based oversight.

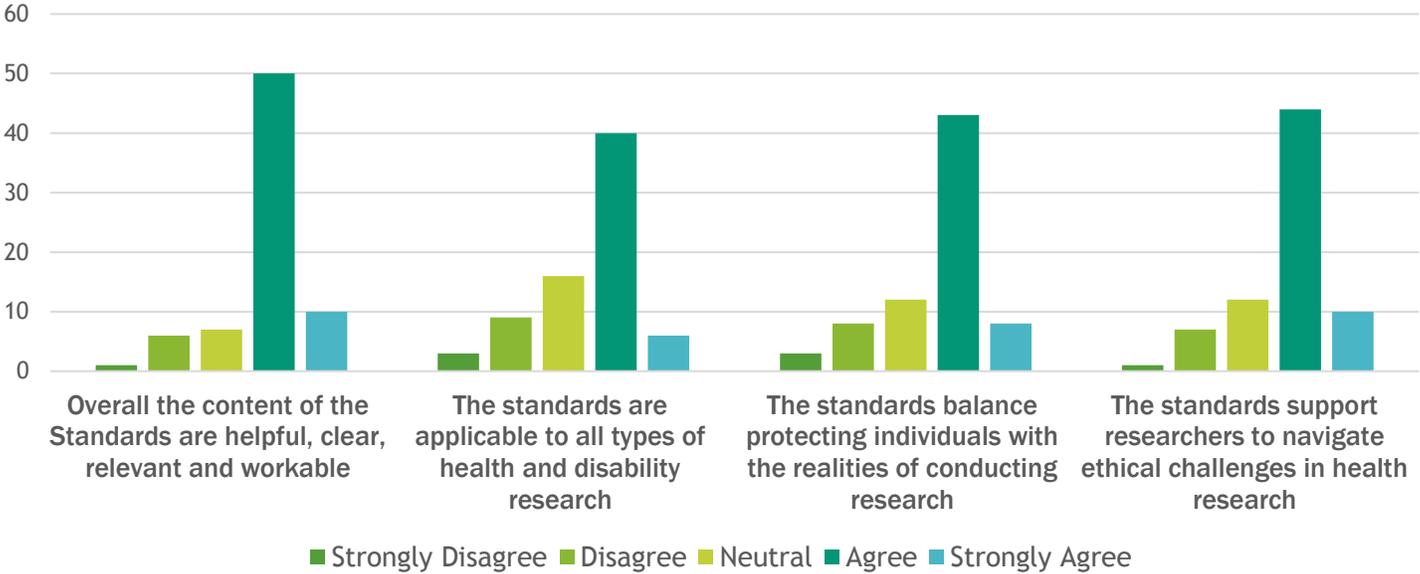
Knowledge advancement; gaps in ethical guidance

NEAC asked submitters to identify areas of ethics that were not covered. The following are those NEAC will address.

- IDI data and health research using the IDI.
- Emerging technologies such as CRISPR, algorithms / machine learning, and artificial intelligence.
- Post disaster research, emergency research, and pandemic research.
- Disability research
- Knowledge generation activities (that may not be research)

Fit for purpose

Fit for Purpose



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

Overall, feedback was positive about the Standards being fit for purpose, described as ‘*generally clear, helpful and comprehensive, covering most ethical issues or concerns present in research*’. The document was described as comprehensive, succinct and workable, although many submitters, including those who were positive about the document, also made specific comments about where clarity could be provided, or areas that could be simplified.

A number of submitters noted the hyperlinking between concepts was very helpful, and made further practical suggestions to enhance the usability of the document, such as the inclusion of a flow chart, glossary, or some mechanism to enhance finding information. One example was to add page numbers included with the hyperlinks in order to assist linking when using a print document, another was to use colour coding to differentiate standards from guidance.

Many submitters noted that while generally the flow between standards and commentary was good, there were cases where the commentary may require being brought up to the level of a standard, or cases where it was unclear what standard the commentary was referring to. Structure and internal consistency (for example the use of ‘must’, ‘should’ language in places outside of standards) has been identified as a key theme from the consultation, and comments relating to structure, standards, and commentary have been summarised in the high level themes section.

A few submitters had concerns about enforcement and implementation with regards to the Standards and their impact with the wider ethics system.

“These guidelines provide well-grounded, clear guidance to researchers about the ethical dimensions of research. The level of detail is good, and the language is easy to understand. The ethical principles applied and expressed resonate with literature and the ethical principles recognised as relevant to research locally. A wide range of potential circumstances are discussed, and the principles are expressed at an appropriate level of generality”

A few submitters focused only on some sections, and did not want to comment on the document in its entirety. One submitter, while noting that overall the document was worthy and well considered, expressed concern that the commentary sections were pre-empting or justifying the NEAC position on particular standards in advance, which is not necessary for a standards document and could limit their application. One submitter requested all Te Reo to be defined in-text, to assist with the flow of the document. One submitter observed a difference in quality between different chapters in relation to both content and integration of Māori concepts, and suggested areas to further develop.

A number of submitters held concerns about the length and complexity of the document overall.

“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.”

A few submitters held the view that generally the standards were fit for purpose, but had concerns relating to particular areas that they wanted to draw attention to, particularly research with children and the concept and management of disability research. Also, from a fit for purpose and workability perspective, it was noted that the document was inaccessible to people with disabilities. Suggestions were provided to improve areas that overlapped, improve the structure of the document, and to enhance clarity of statements. One submitter thought that the Standards did not fully embody the participant stance, appearing practitioner or bio-medically biased.

It was duly noted that referencing in the document requires review.

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

Many submitters were positive about the wide range of ethical coverage. There were also a number of specific areas raised that required further clarification, for example research with participants who had a terminal illness.

“The standards have sufficient breadth and depth to enable researchers to apply the principles in a range of contexts”

The addition of innovative practice was well received. It was noted that the coverage was weighted towards clinical research, and that other kinds of research needed to be addressed to ensure ethical coverage was complete. Submitters noted that observational research, qualitative and ethnographic research, and studies

involving standards of care required more attention. In particular, more guidance on proportionality would be helpful in order to know how to interpret the standards for lower risk research. Other research types that can occur in the grey area, such as public health interventions, were noted as unclear about guidance and coverage. Disability research was also raised as an area that needed further clarification.

One submitter noted that some future technological developments, such as deep learning tools or software that could 'replace' clinicians, posed ethical issues for current and future researchers.

Some submitters were unsure whether the document was supposed to be applicable to audit and related activities, which resulted in uncertainty about the ethical coverage. The scope of the standards was raised as being potentially too broad, with a few submitters requesting more clarity on the distinction between research and non-research activities.

Translational research was also raised as a crucial area that needed guidance and definition.

Disability research was noted as being underrepresented, with issues around interpretation and understanding of disability concepts.

“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”

Quality improvement was cited as a complex ethical area, and guidance was sought from NEAC on this issue.

The Standards balance protecting individuals with the realities of conducting research

Most submitters were positive about the balance achieved in the document, noting the difficulty in achieving this. Balance was explored in many different ways, for example balance between facilitating research and protecting participants, and between balancing risk and balancing the level of information in the actual standards. Submitters noted the focus on ensuring protection for potentially vulnerable participants, privacy, and confidentiality. Submitters recognised how balance is present in many practical circumstances, for example, in clinical trials with new medicines where privacy is weighed against keeping health data potentially identifiable, in order to be able to identify individuals for safety 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.”

A submitter thought that where standards were aspirational they should be indicated as such, to recognise that the document does aim to develop future practice as well as provide clear guidance for the current research environment. One submitter noted that there needs to be balance between protections of

participants that recognises that research governance needs to be proportional, so as not to burden researchers.

Some submitters raised concern with the standards not recognising the realities of conducting research, with regards to ethics and local processes. This related to research with Māori, and addressing the practical requirements of consultation processes. A few submitters noted that some of the attempts at protection

“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”.”

could in fact adversely impact participants, noting the length and complexity of participant information sheet requirements. Requests for NEAC to address how to balance information and length was made. Some submitters noted that particular sections required more sector feedback, in particular stem cell research. Another risk that was raised in the context of protecting participants was in relation to compensation for commercial trials, and what the Standards’ role was in protecting participants even though this was an issue relating to regulation and law outside of the remit of the ethical standards. Submitters also noted that the

“The reality of conducting research involves 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.”

law, with respect to participants who could not provide their own consent, resulted in the standards under-protecting this group from harms resulting from lack of research. Similar views about disability were made with regards to the need to ensure inclusion and accessibility.

“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.”

One submitter stated that the balance privileges western individualism, and requested that the standards ‘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’.

The Standards support researchers to navigate ethical challenges in health research

The majority of submitters described the Standards as useful and comprehensive, agreeing that they should help researchers navigate ethical issues. It was suggested that linking back to the ethical principles at the top of the document would help remind researchers that it is these principles that enable ethical reflection

for particular issues. The combination of Te Ara Tika and traditional bioethical principles enables a broader approach to different ethical issues. As with other sections, more cross referencing was requested. This question drove feedback around some groups that were not represented, as outlined in the high level themes. Extensive feedback was received on the topic of autonomy and independence, highlighting the need for recognition of other forms of autonomy, such as dependence, interdependence, and relational autonomy.

“Regarding disabled researchers there is consideration to be given to the design of research processes and how ethical considerations interact with meeting reasonable accommodations needed for them to be successful in their work. For example, the role of support workers may need to be considered where they are engaged to carry out tasks relating to the research as an extension of the disabled researcher’s autonomy.”

Vulnerability was also explored in depth, and NEAC recognises the need to balance protection without paternalistic or outdated thinking. Similarly, a more nuanced approach to the concept that recognises vulnerability as something researchers need to think about universally and contextually is needed.

Consultation was suggested to include more guidance for researchers on how to navigate and meet the principles.

“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.”

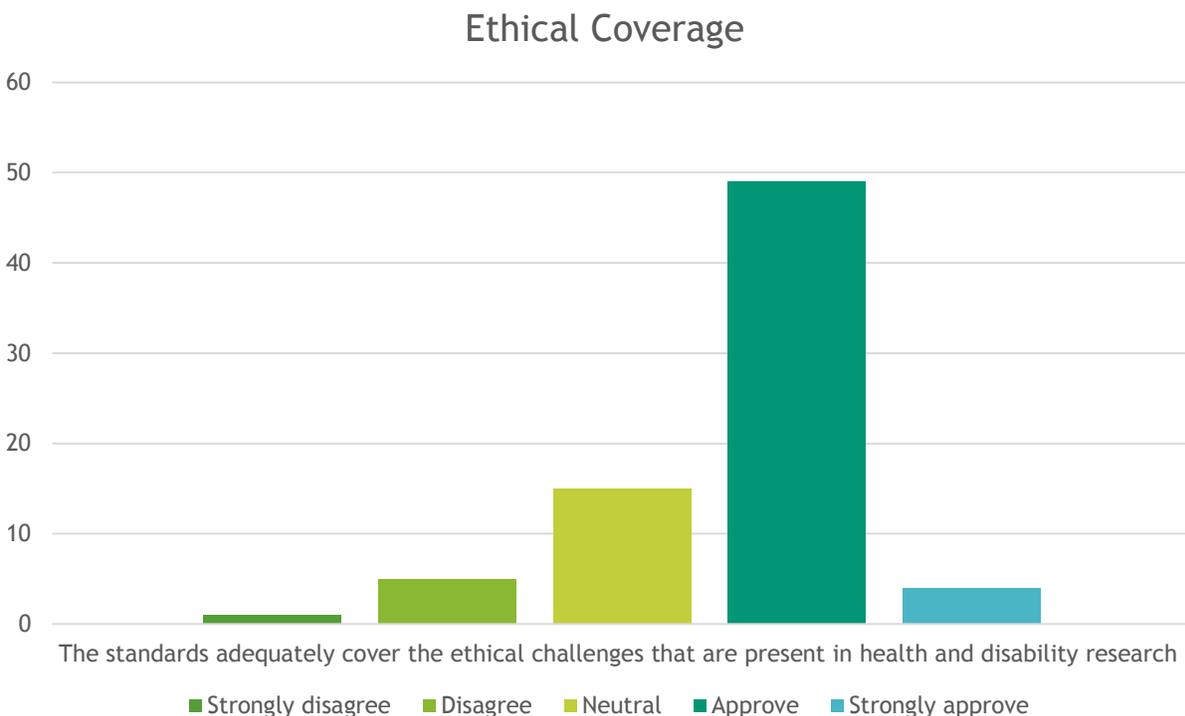
Navigation of the document itself was raised, with suggestions on how to enhance navigation. A submitter noted the importance of the Standards to be supported by other guidance materials, such as updated participant information sheet templates and other common ethical issues guidance.

Coverage of Ethical Guidance

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

The majority of submissions expressed satisfaction with the guidelines' coverage of major ethical issues. Of submissions which were generally complimentary but raised additional concerns, problems with the draft's lack of commentary on disabled participants were most frequent, such as conflating health and disability research and offering only a restricted definition of 'disability.' The section on stem cell research was also seen as in need of improvement by one submitter.

"Much of our concern again stems from ensuring the disabled people's voices are valued as equal to non-disabled people's voices in both disability specific and broader health research. We wish to see disabled people recognized and valued as experts in their own experience."



A significant research area thought by many to be inadequately addressed was data governance, specifically in the need to future-proof ethical guidance against rapid advances in technology. Insufficiencies were alluded to on the topics of linking de-identified information, such as IDI data and the use of health information without consent. The importance of keeping the guidelines "live" and regularly reviewing its content was stressed by submitters.

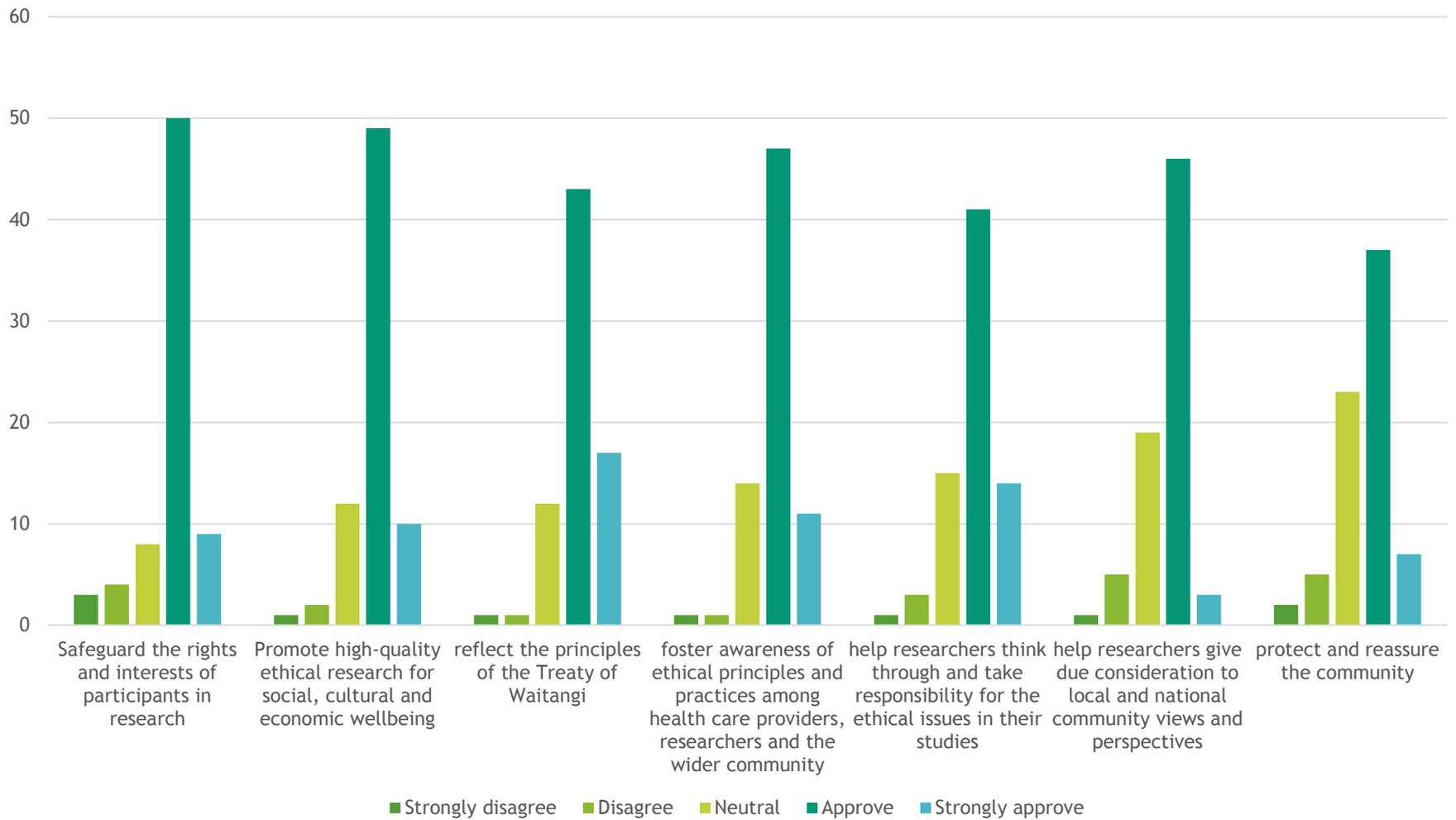
“...advances in data science are swift. Software and machines will replace health care professionals in some areas. Have you addressed all the ethical issues around this, e.g. should patients always be able to choose between human and machine?”

A recurring criticism noted that the guidelines, while comprehensive in its treatment of Māori cultural issues, was relatively silent on other ethnicities involved in health research. Other submitters demonstrated that there is tension between the values of inclusivity and protection of Māori, where Māori DNA is automatically excluded from research.

Considerable challenges were said to be encountered by a number of people when engaging in research with individuals with diminished cognitive functions. One submission emphasised the importance of conducting these kinds of studies, and that advice on doing this ethically, for example in securing consent, is lacking at present. The LGBTIQ+ community introduces ethical challenges which hinder participation as well, and another submitter requested that the guidelines be improved to address this.

Additional guidance gaps were pointed out in isolated comments. One was said to appear when multiple people interested in the welfare of participants disagreed on said participant's inclusion within a piece of research. This related to feedback from another person who commented that there was no clear solution offered for when ethical principles come into conflict. There was further confusion around consent for the use of tissue in paediatric bio-banks, CRISPR research, and a “grey area” where ‘clinical studies’ are equated with ‘clinical testing’.

Overall, the Standards...



Scope of the standards

Merging the observational and interventional guidelines

Most submitters agreed with the merging of the 2012 guidelines into one document that covers ethical standards for both observational and interventional research, as many research proposals involve elements of both. However, it was also noted that there is a need to emphasize points of difference, as some standards may be interpreted differently when applied to observational and interventional research.

One submitter noted there may also be a need to have a separate note on clinical trials, socio-behavioural research, and research using traditional medicine. Similarly, something on ethical aspects of emerging technologies such as CRISPR, Nanotechnology, and Synthetic Biology.

Two submitters noted that the combined standards remain silent on audits and registries, and requested that more information is provided for these non-research activities.

Submitter views

Overall, the merging of both observational and interventional guidelines is beneficial and makes clear the standards that apply to each type of research.

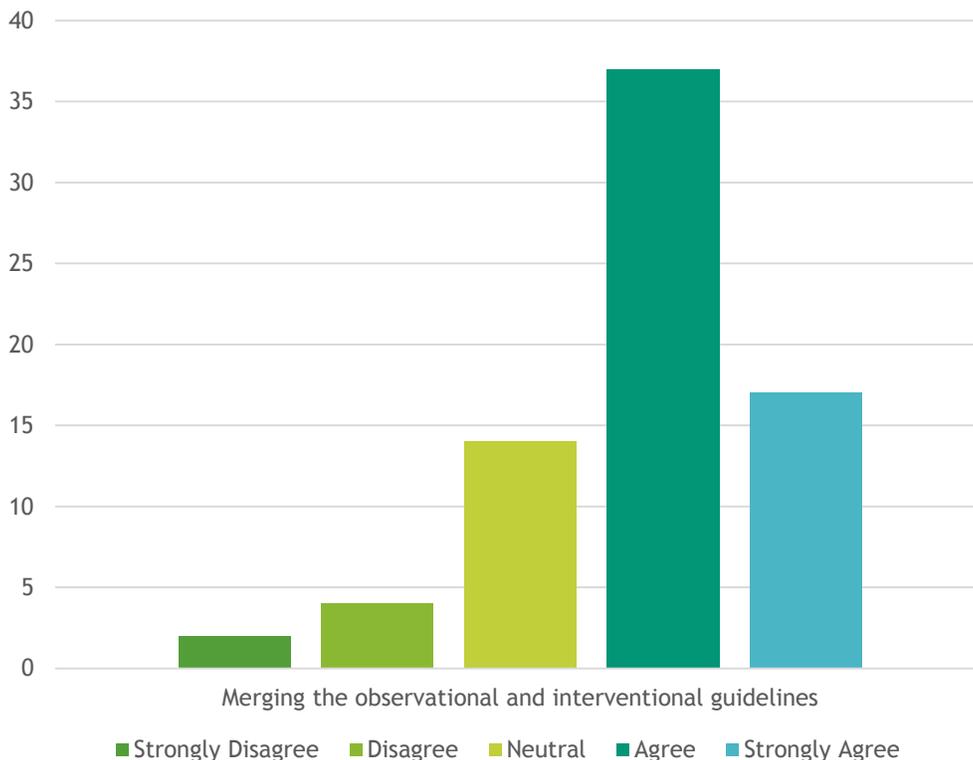
The guidelines are appropriate for clinical trials and interventional research but less relevant for observational research, which is poorly and vaguely described.

The Standards assume that research is paradigmatically interventional and clinical.

We believe combining the interventional and observational standards was a good decision.

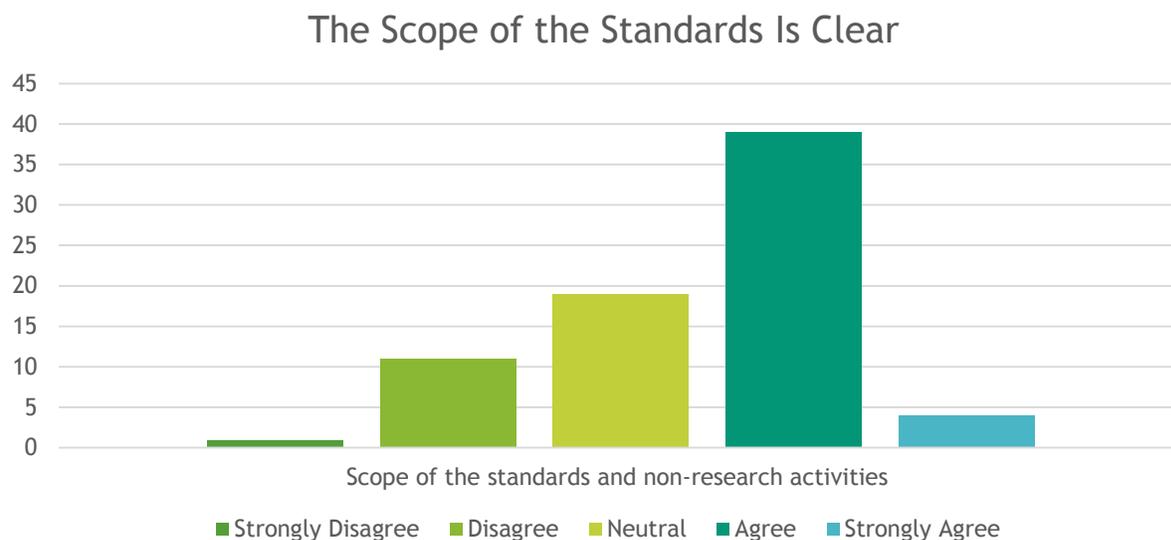
I think it is a big improvement having one document - this will make it much easier for all the studies that include a mixture of observational and interventional research.

The Standards are applicable to observational and interventional research



Scope of the standards and non-research activities

Most submitters who commented on this section agreed that although it is very difficult to define research, the Standards make a great attempt to define research in line with international guidance. It was noted that the inclusion of a table of activities regarded as 'non-research' was also very helpful. NEAC noted that they would further develop this guidance to assist researchers.



Many submitters expressed that the scope between research and non-research is still not clear enough from the researcher's end, given that the standards scope also applies to non-research practices. The scope issue was both in relation to what is research, and also in relation to what is 'health' and 'disability' research. Some submitters queried where they would go for evaluation activities if ethical review is not undertaken. Submitters noted that if there is 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, otherwise there could be a risk that committees and researchers are making their own decisions about scope which may not be informed or nationally consistent. One submitter noted that the Standards appeared to apply to any scope of research, in terms of size – NEAC acknowledges that proportionality is appropriate, but this should be based on risk. There was support among submitters for the use of the WHO terminology in relation to wellbeing.

One submitter suggested that the document could be made better by adding summaries, flowcharts, and diagrams to determine a clear pathway. More examples were requested of non-research activities, including activities undertaken routinely by DHBs, as directed under the New Zealand Public Health and Disability Act.

Innovative practice

Overall the section on innovative practice was well received by submitters and considered a useful new section. Its place in the context of the document was discussed by some submitters.

"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."

One submitter suggested it would also be useful if this section discussed the issue of "case studies" in research.

It was suggested by one submitter that input from the DHBs, private hospitals, and professional bodies could be sought to strengthen the innovative practice section. The scope of innovation requires broadening, as one submitter noted, *'the proposed definition of 'innovative practice' is too narrow, and the description of its application is exclusively medical.'*

"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."

Audits and related activity

Submitters made comments on audits and expressed that the definition could be strengthened so that there are fewer barriers to conducting audits and related activities. Having clearer guidance is highly recommended by a number of submitters, and some noted that words like *research* and *wellbeing* could be better defined.

The difficulty with definitions of programme evaluation were raised by some submitters. This raises the question of whether some programme evaluations should be considered research, and exemplifies the difficulty with categorical definitions.

"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."

Ethical principles

Fit for purpose

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

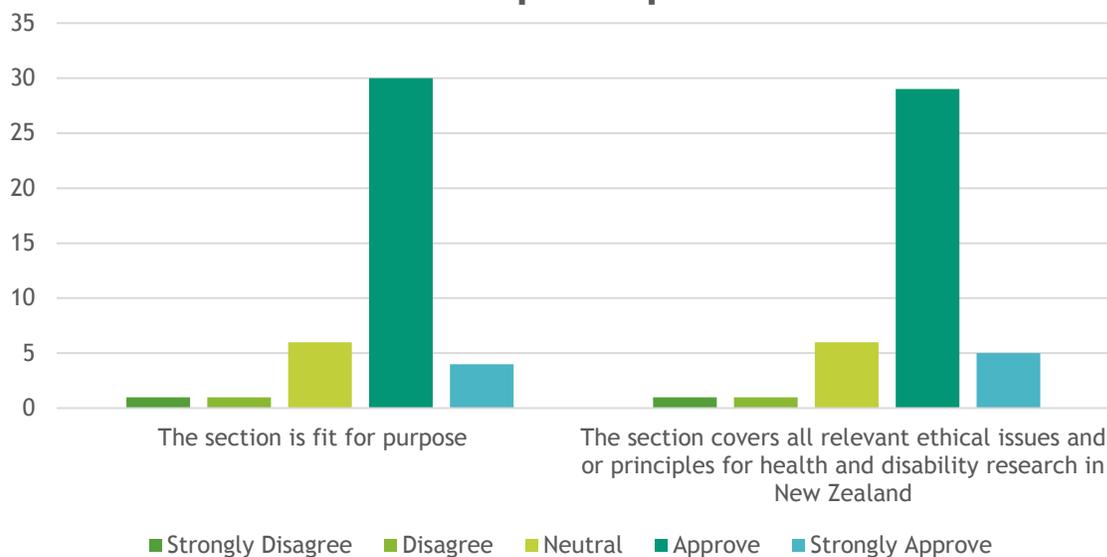
“We value the way in which Te Ara Tika principles and bioethics principles dovetail and complement each other while offering unique and important contributions to the ethical standards and way in which research is conducted in Aotearoa New Zealand. The inclusion of both sets of principles, and the way 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.”

“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 trend of generally favourable feedback continued here, with many people thinking the section provided useful framing for the forthcoming material. Praised in particular was the way in which Te Ara Tika principles and Western bioethical principles were aligned and used to ground guidelines for research in multicultural New Zealand. One submitter commented that this could be complimented by greater acknowledgment of Treaty principles, such as partnership, participation, and protection, which are arguably more foundational. Others suggested that principles of disability research specifically might be included as well. Two people disagreed with the above: one criticising the emphasis the document placed on Treaty commitments, the other thinking that these two streams of principles were “confusing and overlapping.”

The weight of critical feedback fell on the presentation of the Western bioethical principles. One person thought the standards glossed over recent debate in bioethics, which implied that the Western approach is unproblematic. For example, little guidance is offered on how to prioritise principles in cases of conflict. This was supported by a recommendation that section 5.3 include citations for the claim that “The bioethics principles are widely recognised.” A different submitter claimed that the bioethical values were not originally intended to apply to research, and therefore omit the researcher’s obligation to advancing knowledge. The inclusion of a ‘principle of research merit,’ was proposed. One person suggested updating the term ‘non-maleficence’ for contemporary readers, and was unsure whether section 5.8 matched the order given in Figure 1. The same person thought that 5.8 drew an extreme conclusion from the principle of non-maleficence, where their position was that research risks should be minimal, regardless of expected benefits.

Ethical principles



“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 be subsidiary to their ethical obligation to the welfare of research participants.”

The view was that this may result in requirements put upon researchers that are disproportionate to the actual risk of harm. NEAC acknowledge the need for proportionality of ethical oversight in relation to risk.

Ethical coverage

Five submitters confirmed that all relevant areas of ethical concern were covered. Others considered issues surrounding privacy, participant compensation, and communication as in need of expansion. One person noted that the document repeatedly mentions ‘independence’ as an ethical priority, and thought it would be helpful to describe how this goal relates to disabled individuals; a definition of interdependence and a declaration of its importance in the ethical landscape was also thought worthy of inclusion.

General feedback

Section 5.7’s treatment of the Te Ara Tika principles and their relation to research drew the most sustained response. The importance of manaakitanga led submitters to suggest that researchers should have a specified means of communication with participants. It was also noted that collective participation goes far beyond “establishing goals and benefits of research,” and begins rather with the research agenda and institutional arrangements. People proposed the manaakitanga sub-section’s wording be updated to reflect this. One person did not find it clear how love and generosity operated in health research, and requested that the guidelines provide some examples. Additionally, the explanation of tika was said not currently to

allow for research not showing success of an initiative. Both the tika and mana sections were also seen to lack prescriptive statements directing researchers' actions.

Concerning paragraph 5.8 and the Western bioethical principles, submitters questioned the change from the principle of autonomy to 'respect for people.' In particular, it seemed that issues of autonomy were primarily what the document discussed. Other submissions requested that the non-maleficence principle be stated more strongly, insofar as the risk of harm should be "completely minimised" and not simply "reduced." A trend in the feedback also saw people criticising the Western and Te Ara Tika principles as overlapping; for example, beneficence with tika and manaakitanga, and non-maleficence and justice with mana. Feedback also addressed the visual overview in 5.6 of the 8 ethical principles. The structure of the table confused one person who thought each Māori principle had a corresponding bioethical counterpart. They suggested that a circular diagram placed earlier in the document would keep others from making the same mistake.

Remaining comments were distributed across sections 5.3, 5.10, and 5.11. Two submitters raised concern with the bioethical principles being positioned as undisputed. Effort should be made, therefore, to mention alternative ethical theories in 5.3. In 5.10 a number of people took issue with one principle being justified by another. A principle of autonomy, for example, was thought unable to be founded on a principle of respect for persons. Likewise in 5.11, submitters advised that principles cannot be both equal and supreme. Moreover, while these sections seemed to foresee conflict of principles, people judged them as in need of further guidance around what researchers might do when this is encountered.

"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."

NEAC recognise that there are a range of means to determine ethical conduct, including other forms of ethical analyses than principlism. Some further guidance in managing conflict between the principles will be included, however the important aspect is to recognise the conflict and explore it consciously. Some submitters noted that a principle of merit, and the principle of relationships, were not present in the traditional bioethical framework. However NEAC note that when both ethical frameworks are available and in partnership, the breadth of coverage is much broader than having only the four traditional bioethical principles. Te Ara Tika can fill that gap. Two poles in the submissions were identified: researchers who want restricted minimalistic guidelines, and 'philosophers' who raise lots of questions but not much guidance. The middle ground was noted to be the ideal: to develop principles which support people to feel "safe on shaky ground", and also don't hinder health research. NEAC support the view that the principles are guides, not rules, and will be clearer about this.

Research involving Māori

Fit for purpose

Overall, submitters were positive about this chapter, commending its focus on fairness and its high degree of context. Submitters agreed that the Standards highlight the importance of early Māori consultation and constant engagement with Māori throughout the research.

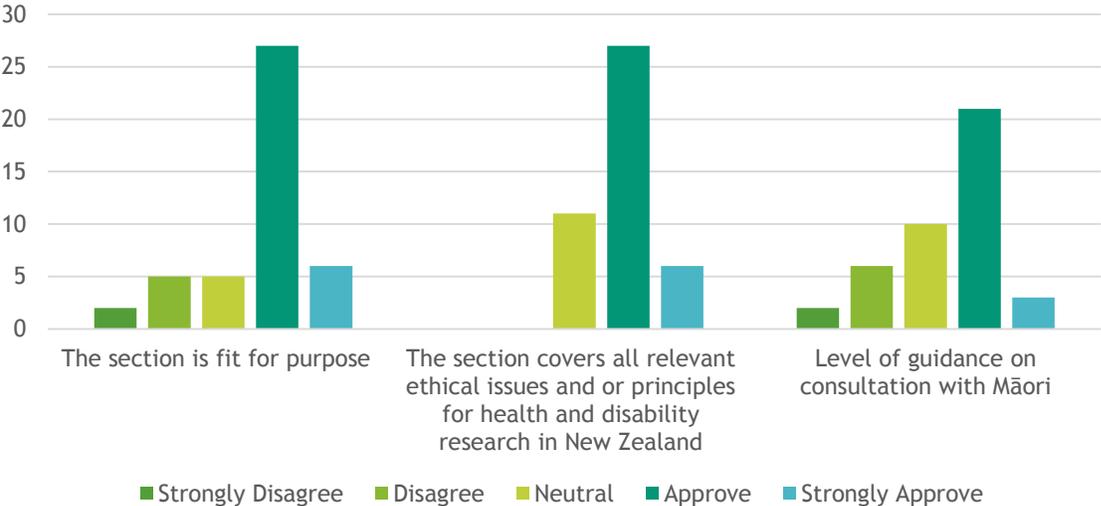
Submitters widely acknowledged and supported the focus of this chapter and its importance. Clarity was requested for the definition of some new concepts and how researchers could accurately apply them, such as cultural rigor.

“Te Ara Tika gives excellent guidelines in this regard, and this section is clearly modelled on that advice in a pragmatic fashion.”

“This is clearer than the previous standards and makes clear to researchers what is required.”

“This section has potential to be a powerful influence on research integrity and enhancing the environment for Māori health research. There is room for improvement nonetheless.”

Research involving Māori



One submitter noted there is no standard to reflect that researchers should maximise the degree to which their study can contribute to Māori health outcomes.

The acknowledgement in section 6.19 of the realities of international clinical trial design was appreciated. In the case of international clinical trials, it is anticipated that engagement and involvement with Māori 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. One submission was concerned that the current wording regarding adapting protocols may be unintentionally perceived as a barrier to involving New Zealand in international clinical trials.

A few submitters commended the Standards but suggested that most of the standards in this chapter also apply generally to all other research participants, but noted the appropriate re-enforcement that it is especially important in research with Māori.

One submitter noted that the document could be clearer at positioning Māori as initiators and designers of research as well as participants. There could also be a clearer commitment to data sovereignty (ownership, self-determination) rather than simply sharing data.

One submitter thought that there was a need for the Treaty to more explicitly underpin this section.

The practicalities of consultation were raised frequently, including comment on the current review systems in New Zealand.

“This chapter gives much needed guidance on consultation with Māori. An issue arises with the requirement to engage with Māori ‘who have sufficient knowledge to play a meaningful role’. These individuals are rare and it can be very difficult to identify Māori 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.”

Ethical coverage

As to whether the Standards cover all relevant ethical issues, one submitter noted that the Standards use principles that are certainly well known and widely used, but suggested additional Treaty principles that are also relevant to ethical considerations, and have been identified in New Zealand case law and by the Waitangi Tribunal. Suggestions include the principle of rangatiratanga, the principle of equality (rite tahi), the principle of redress (whakaoranga), and inclusion of the Māori terms for partnership, participation and protection, namely ‘mahi tahi’, ‘whai wāhi’ and ‘kaitiakitanga’.

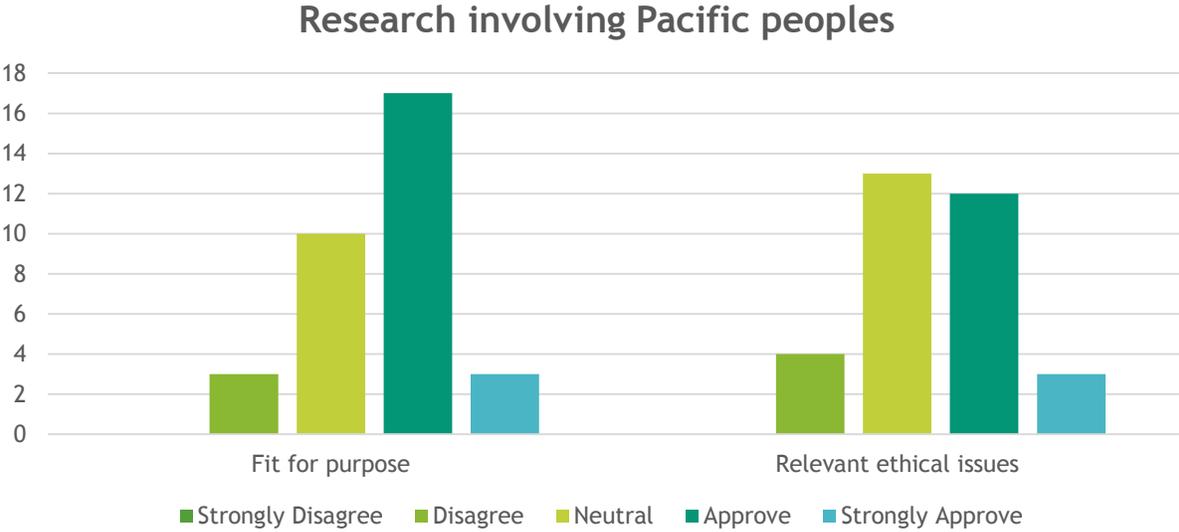
One submitter suggested throughout this section that use of the term ‘consultation’ should be critically considered with a view to replacement with the concept of ‘participation’ to better align with the Treaty principles previously highlighted in the document.

Consultation, participation, and engagement were explored comprehensively.

Research involving Pacific peoples

Fit for purpose

The section received support, with those rating the section positively stating that it was easy to follow and included practical guidance. A common theme was the need to strengthen the language in order to reflect the equity issues that need to be addressed by health and disability research.



Some took the view that the Pacific peoples section should be a sub-section of the Research Involving Māori. Feedback suggested that it was confusing that this section looked different from the Māori section. Language used was also commented on, stressing the need to reflect the diversity in the region. Better addressing of the sets of values that underpin Pacific methodologies like Talanga and Talanoa were requested.

A few submitters stated the section lacked clarity on what researchers should be doing as a result of the guidance and information. One submitter stated that when compared to the section with Māori, the Pacific section felt outdated and generic.

Feedback on this section was mixed with most submitters agreeing that the section was easy to follow and contained the right ingredients, but could, and should be strengthened. Submitters gave many helpful suggestions about how this section could be strengthened.

Submitters supported the guidance provided to researchers regarding the involvement of Pacific people in research and the specific cultural factors that should be considered in research involving these groups. Conversely, submissions also noted that the Pacific section repeated much of the considerations for Māori, with a suggestion that the Pacific section could be trimmed down to purely Pacific considerations.

A number of submitters expressed their view that the research with Pacific section should follow the same layout and levels of consultation, using models similar to those used in the Research with Māori section.

There was a suggestion from one submitter that the Pacific section should be a subsection of the Māori section.

Ethical coverage

Some submitters noted that although the Standards attempt to be inclusive by using the phrasing Polynesia, Micronesia and Melanesia, the section is 'Polynesian', and assumes that all Pacific people share the same values. This section could be improved to include all principles such as Ofa, Malie, Mafana, and Faka'apa'apa so that everyone is able to recognise the wording.

More specifically, a number of submitters noted that the draft guidelines uses terms that are all Samoan, and suggested that the Committee broaden the terms so the rest of the Pasifika/Pacific peoples are not excluded from the standards.

General feedback

A number of submitters used this section to discuss the use of the terms 'must' and 'should'. NEAC will review these comments and make the necessary changes.

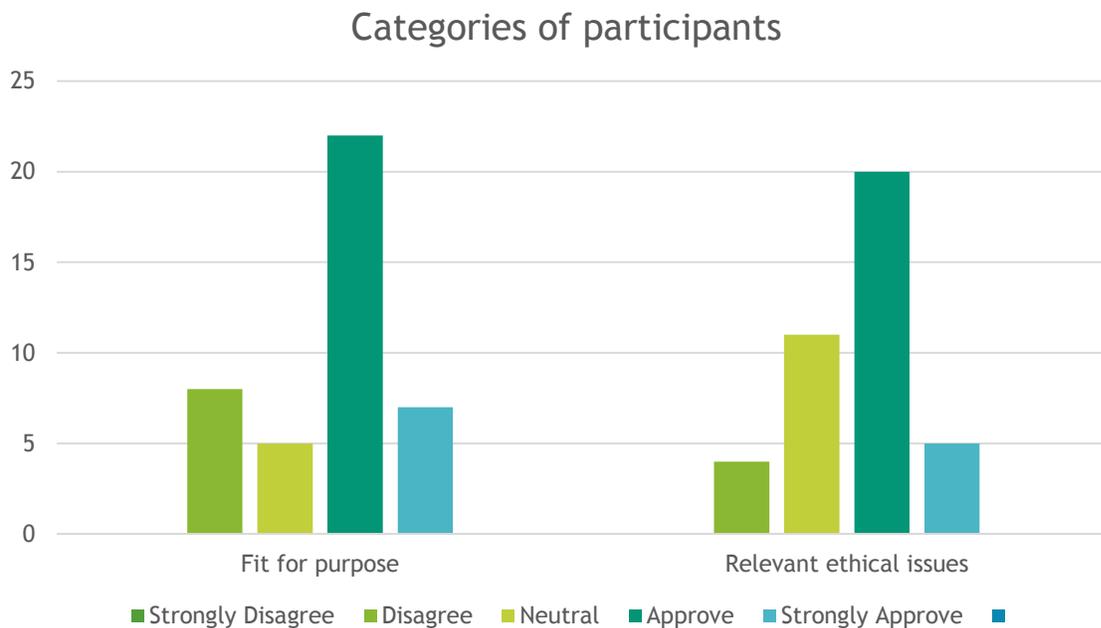
Categories of participants

Fit for purpose

This section was received positively by submitters who expressed that it was easy to understand and comprehensive. A number of submitters particularly liked the insertion that researchers shall not exclude participants from research simply because they belong to a group traditionally considered vulnerable.

Submitters noted that the section contains helpful guidance for researchers, it was understood that there is a difficulty of simply listing vulnerabilities in the section, as well as all potentially vulnerable types of participants and the particular emphasis on their increased risk of harm.

Some submitters appeared to dislike the term 'vulnerable' and found it disempowering. Following on from this theme, submitters noted that it is very difficult to be able to cover all potential vulnerable groups and suggested that the Standards should instead have clear principles of participation that are adaptable to multiple groups including a clearer definition of 'vulnerable' and less emphasis on specific groups as such. Others wanted more categories included, and for the standards to be explicit about increased protections for these groups.



Many helpful suggestions for further categories that could be added to this section were expressed, including but not limited to those who are in multiple categories of vulnerability, LGBTQIA+, and people for whom English is not their first language. It was also suggested that gender neutral pronouns be used throughout this chapter.

One submitter noted they were particularly supportive of paragraphs 8.13 and 8.14 as vulnerable groups have a right to participate in research, even though it may require researchers to take extra measures in designing their research.

“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.”

“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.”

Ethical coverage

One submitter requested that there be an extra sentence stating that when research is done in vulnerable groups it should be done in partnership with them, and steps should be taken to ensure that participants and the wider community are comfortable with the research.

It was noted that it is important to describe the vulnerability itself rather than label people or groups. A theme in general was that clarity of terminology is important and requires careful consideration.

“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.”

There were a range of views around balancing participation of groups such as children or people unable to consent for themselves, and preventing exploitation of them.

NEAC appreciate the need to move away from paternalistic language, and noted that they had explained in the draft Standards that vulnerability was not based on groups but was more of a flexible concept, however this can be made clearer in order to balance protections for people and groups as well as recognising the need to have research be accessible for all.

General feedback

Submitters explored the ethical tension present when researching with people who had diminished capacity to consent. Concern was raised by one about the ability for researchers to make determinations about whether participation was in an individual’s best interest, and whether family members were able to make a reasonable decision without being coerced or feeling under duress due to the circumstances. It was suggested that in cases where capacity is limited, including with children, that the right to protection must be higher. It was also noted that 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.

The view that groups of people are vulnerable again received mixed views about whether this helped or hindered their place in health research.

“Positioning children and young people as vulnerable participants limits their opportunity to have their voices heard, influence health services, and be included in health research. It would be better to acknowledge the importance of meeting children’s needs when including them in research rather than suggesting we should only conduct research with children when we can’t gain the answers from adults. It is very important that children and young people have the opportunity to contribute to research about issues/decisions that affect their lives. Health and healthcare are likely to be issues of significance to children.”

Concern was also raised about the barriers to conducting dementia research in New Zealand.

Informed consent

Fit for purpose

Feedback received on the informed consent section was mostly positive, but substantive, with submitters recognising the substantial scope of the section. There was also common feedback that the section was difficult to navigate.

While consent was mostly described as a process in the Standards, there were still some cases of consent using language such as “obtained”, which should be revised to reflect the view that consent is a process.

A number of submitters noted the importance of recognising different consenting methods, such as opt out, integrated, and abbreviated consent. One submitter was pleased to see the precognition of the potential value of new consenting technologies, such as electronic consent. Further guidance was requested on using these new methods. Some concern was raised with altered forms of consent. For example, with opt in consent would participants just ‘go along’ with what was proposed?

“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”

The requirements for consent were noted to be clinically weighted, and this required balance if the Standards were to be applicable to other kinds of health and disability research. A number of submitters raised the need to recognise the difference between informed consent in clinical contexts to other contexts.

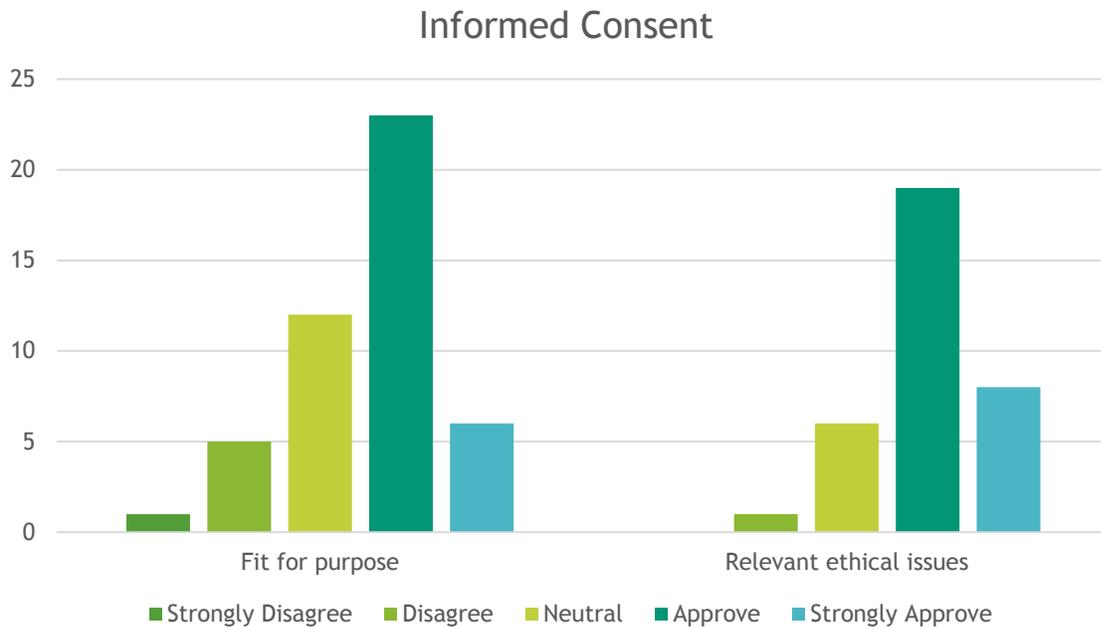
There were calls to bring sections relating to informed consent that were found in other chapters all into the single informed consent chapter.

“...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.”

Critical feedback related to informed consent in relation to disability. The legal context for consent was described by a number of submitters.

A strong theme was the need to somehow balance the long list of requirements to meet informed consent with shorter participant information sheets.

“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.”



One suggestion was to require lay input into participant information sheets, with another option being a lay summary.

“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 received substantial feedback about internal consistency and structure in line with high level themes, addressed in the high level theme section of this document.

Ethical coverage

Submitters were positive about integrated consent and requested further guidance on where opt out consent was ethically appropriate.

“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.”

A few submitters noted that assent could also be in this section, rather than the categories of participants section. There should be provision for more flexibility around children's assent/consent when ill and under stress. For such children, parental consent should suffice, at least until they are in an improved condition. Abbreviated, staged, and verbal consent should also be considered for children and adults when very unwell and distressed and needing clinical trial treatment urgently.

Verbal consent required further guidance as to when it is appropriate.

One submitter explored the need for a relational ethics principle that could assist in considering informed consent from a viewpoint other than autonomy.

“The main discussion of ethical principles earlier in the guidelines covers both Western bioethics and Māori 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 Māori 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...”

One submitter asked NEAC to consider preventing commercial global sponsors from "stalking" past participants on open social media after a participant has actively withdrawn consent.

One submitter explored whether the consent forms that are used in standard practice, for example in surgery, could have some wording added in order to have a front door consent that enabled data to be used for health research. This concept requires considered thought.

General feedback

Research with participants who cannot provide their own informed consent

Most submitters thought the updated guidance enhanced clarity for a difficult research context. A few submitters expressed concern regarding research without informed consent generally. Most submitters thought the guidance provided clarified the New Zealand situation, and made it clear that the law must be followed at all times. One submitter thought research without consent was only justifiable against a backdrop of strong protections (legal and procedural) and a clear process for decision making. A further suggestion was a special ethics committee for this specific type of research.

With regards to NEAC’s view on the current law and an alternative risk-benefit approach, there was strong support for the two-step approach to determining whether the risk-benefit ratio of a study was acceptable

when participants could not provide their own informed consent. It was stated to be an improvement over the current 'best interests' test. A number of submitters expressed concern about patient populations being potentially excluded from health and disability research due to the current law and test. An important consideration was who would be making decisions about the steps, including level of risk.

“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.”

“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 approach to the ethics in the draft Standard for research involving participants who are unable to consent is excellent and is stated clearly.”

With regards to the management of the tension between ethics and the law, submitters had mixed views about how the Standards managed those tensions.

“Paragraph 9.6 – The NZ legal system makes it very difficult for NZ researchers to lead cluster RCTs or to take part in international cluster RCTs where an intervention is being introduced at a community or population level. This also results in NZ not being able to benefit from consequent health improvement. Obtaining individual consent in such studies is not usually feasible. Can this legislation be revisited and aligned with international best practice?

Paragraph 9.69 – Again can the legislation be addressed so that vulnerable groups who are not able to give consent can be included in research? We have previously raised this with the Health and Disability Commissioner.

Paragraph 9.82 – Need for legal advice. It would be very helpful for researchers if there was a centralised process for obtaining consistent and expert legal advice when required. Can this be addressed through NEAC?”

Submitters also held contrary legal views to NEAC's statements regarding the law. NEAC appreciate the different legal views and noted this theme in the Core Themes section.

Submitters were unsure what the status of the guidance provided for the two-step approach was, and if this was not currently legal, whether NEAC would provide ethics advice that would be in line with the current law. Submitters also requested more information on proxy consent (consenting on behalf of another adult).

NEAC explored the tension between ethics and the law. NEAC noted the feedback from submitters and reiterated the view that these are ethical standards, not legal standards. NEAC directed the Secretariat to develop one section on ethics and the law, following the format of the Australian National Statement, whereby the tension between ethics and the law is set out clearly, a substantive list of regulation, legislation and law is set out for researchers to be aware of. In a few key areas, it should be noted or flagged where there is legal ambiguity, but there should be no areas where the Standards make determinations on what is or is not legal in New Zealand. NEAC note that this is a shift from the draft Standards approach.

This decision was based on the views that the law was often not written for research, that there are certainly cases in New Zealand where something is ethical but unclear in terms of legality. There are also differing opinions with respect to these grey areas.

“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.”

Research benefits and harms

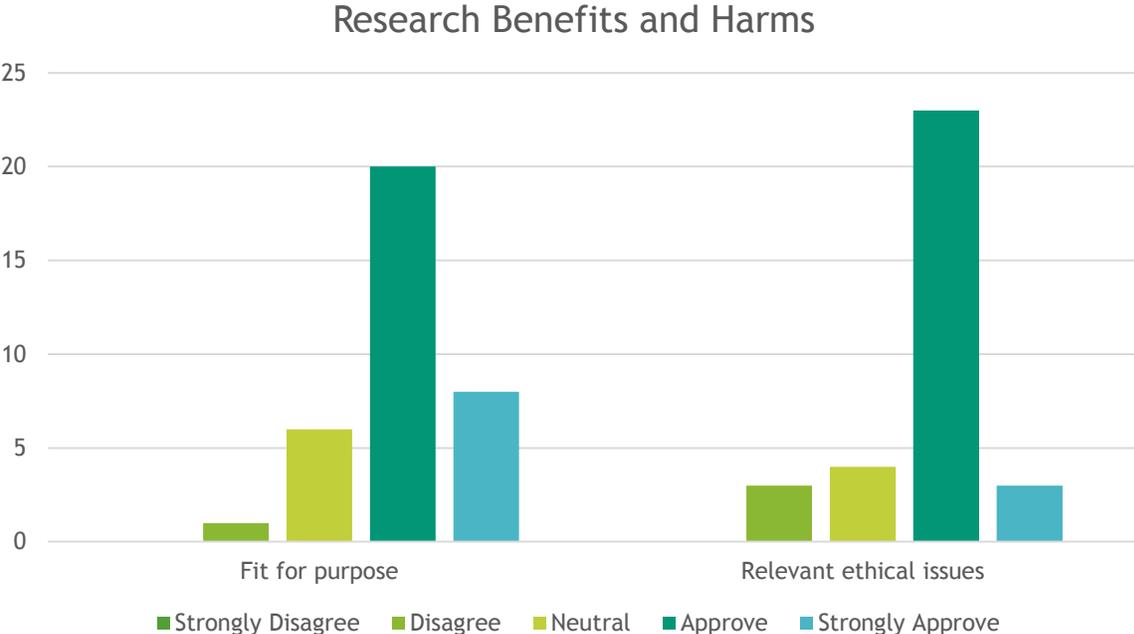
Fit for purpose

Most submitters indicated that the chapter was workable and covers issues appropriately. One submitter stated that it made them think about the actions of research in terms of harms and benefits.

There were some suggested additions to the table of harms and benefits. The explicit discussion on the need to minimise harms was noted, and the ethical issue of participants wanting to participate in high risk research (with potential high benefit) was raised, with the view being that participants should be able to make their own decision if provided with information about the benefits and harms. Another submitter felt that the language was absolute, and could be softened, when it came to describing risk in research. The section also raised a comment about distribution of benefits when considering equipoise.

“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.”

Feedback related to the need to cover both intervention and observational studies, for example many other research domains use mixed methods – for example preventative medicine and public health research. A suggestion was the inclusion of qualitative as well as quantitative research and low-minimal risk/high risk ethics categories. A number of submissions supported the need for clarity around levels of risk, to assist with ethics committee review and ethical oversight of research.



Ethical coverage

Those submitters who felt the section did not cover all relevant ethical issues and/or principles cited the need for clear levels of potential benefit and harm, in order to allow health ethics committees to determine level of risk and therefore level of oversight; i.e. minimal, more than minimal, or high risk. Guidance was also requested on ethics committee review, in terms of where to go for review for different types of research (level of risk and also type/discipline of research). Further work is needed to enable differentiation of risk levels for research projects.

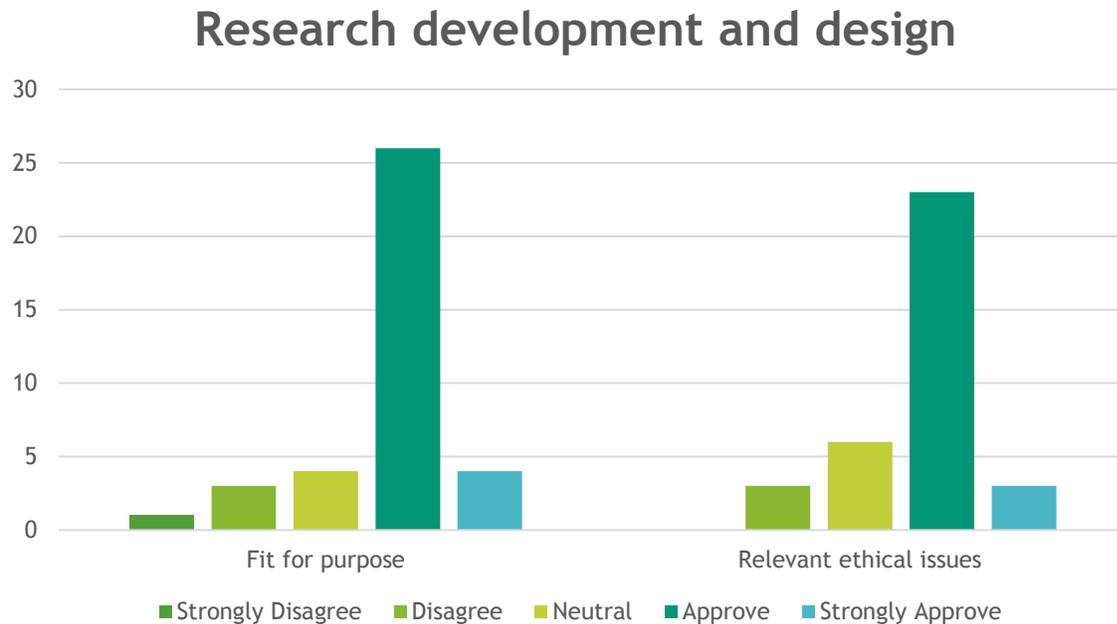
General feedback

Submitters requested that the data section on benefits and harms was combined with the general benefits and harms. The links provided require revision as some of them link to areas that are not directly relevant. Cultural harms were raised by a number of submitters, such as harm to wairua or to mana. Risk of death and permanent disability was also noted as a harm that should be included. Other suggested benefits were the benefit of communities and organisations to attract and retain quality staff, and communities receiving evidence-based care. One submitter stated that harms are also present from not participating in a research project, and this should be taken into account. One submitter also said benefit should not be inflated. A balance between risk and benefit is clearly a key determination in ethical research. The concept of minimal risk was raised, noting the difficulty in proving an explanation of what is minimal risk. A common theme was that there is a need to have different levels of risk outlined, in order to provide guidance to researchers and to ethics committees. The concept of weighing benefits and harms was also raised by a few submitters, and they expressed different views on what risks were justifiable.

“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.”

One submitter stated that the greater good (potential benefits to society and science) must be secondary to the rights and protections of individual participants, and that there is no situation in which the benefit to society and science be given a greater value than the individual, while also acknowledging that it must be up to the potential participant to determine the level of risk they are prepared to accept to achieve the goals of knowledge progression. The submitter noted the importance of researchers understanding this.

Research development and design



Fit for purpose

The section was described as clear and concise, and the detail on what a study protocol should include was helpful for researchers. The linking back to Te Ara Tika was commended.

One submitter raised the need for ethical consideration of inclusion of non-binary people, in particular using two-step method to sex and gender-based analyses (birth and current gender). This matters in health research as it assists with determining population size, health inequities and vulnerability, and ethical considerations. Because sex and gender are key determinants of health outcomes across the globe 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.

Many submitters were unclear about the requirement for equal explanatory power, and whether it was required strongly depended on what the practical impact would be to research. Clarification on when equal explanatory power was required was requested. One submitter felt the information was too heavily focused on clinical trials, noting that proportionality should be applied to different requirements across different types of research. For example, co-design does not require a literature review.

Ethical coverage

The importance of the principal researcher consulting a person with appropriate knowledge, skills, and experience throughout the research process, rather than the proposal being reviewed once, when researching with cross-cultural research, including LGBTIQ+ populations, was stated. One submitter noted Māori views could be better integrated into this chapter.

General feedback

Submitters explored what should or should not be in a protocol. Proportionality with respect to peer review processes was also raised, with some suggesting that all trials required a panel of peer reviewers.

“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.”

One submitter noted some study designs do not need results to be generalisable, so wording should be softened to that effect. Similarly, other study designs such as registries required guidance. A number of submitters suggested that information in this section could be moved to other sections. One submitter discussed the oversight and monitoring of student research. Another submitter raised a question about the term ‘suitably qualified’, and suggested GCP could be a measure of qualification. Suggestions were made to broaden the range of examples for inappropriate exclusion in research, i.e. sexual orientation.

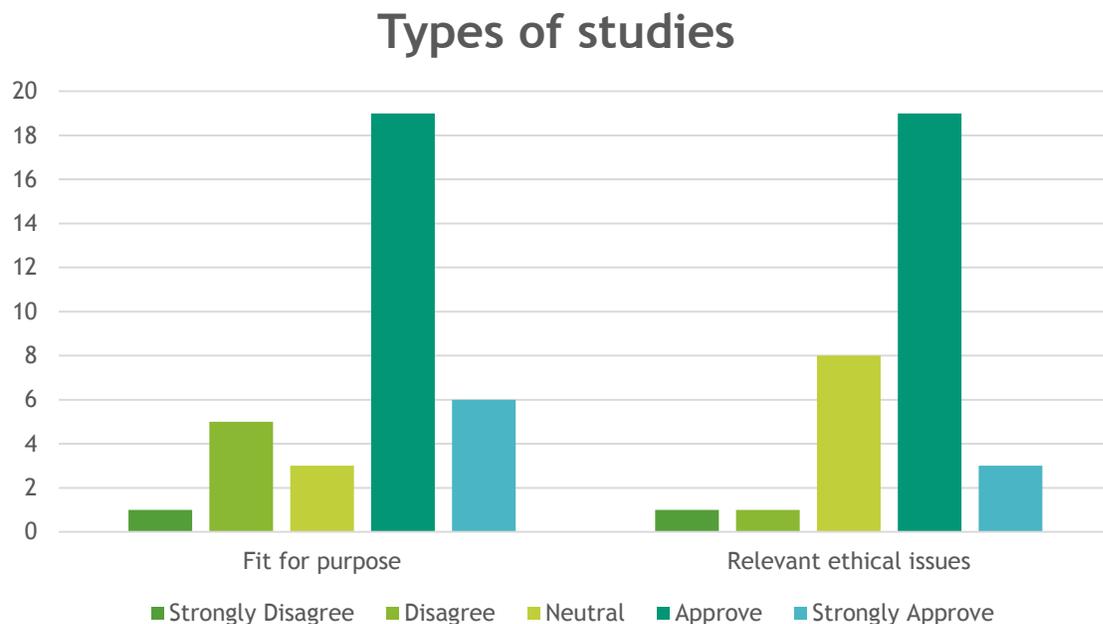
Types of studies

Fit for purpose

Submitters noted that the definitions and explanations of trial types were helpful, and one noted this section could benefit from diagrams. The feedback suggested this section was well outlined.

A submitter noted there is a focus on a clinical model of healthcare research, ignoring qualitative or ethnographic studies. This is inconsistent with the broader scope suggested in the earlier chapter on scope of the document.

Feedback indicated that registries require more detail and audits should be listed under observational studies. Linked data and administrative data should also be covered in study design observational studies. One submitter suggested deleting most of the commentary as researchers who had capacity to plan studies with these designs did not require a lecture about study design. Further linking was suggested, including between cluster design and informed consent.



Ethical coverage

Elaboration on risks of harm in observational studies was requested, as well as commending the point that some forms of data collection can be invasive and therefore very risky.

One noted that 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, i.e. that the design is only appropriate for clinical conditions that can be palliated (e.g. arthritic pain), but not for conditions that can be cured (e.g. acute skin infections). Other issues such as number of cross-overs and wash out periods need consideration. Other missing trial designs that are relevant for New Zealand were equivalence or non-inferiority trials (particularly the use of appropriate active comparisons, rather than inappropriate comparisons such as reduced dose

comparisons). Another submitter noted that wording around needing consent to collect samples in an invasive but low-risk test should be reviewed as it precluded tests in intensive care, such as 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.

General feedback

Submitters presented a number of suggestions that would aid clarification, including further use of subheadings. Submitters proposed minor wording changes, drawing on their experience from various different fields. A few submitters reiterated the need to consider registries in this section. A number of submitters expressed concern about the legal wording and cluster trials. The general theme about increasing inclusion of observational methods was present in this section. ic

Research conduct

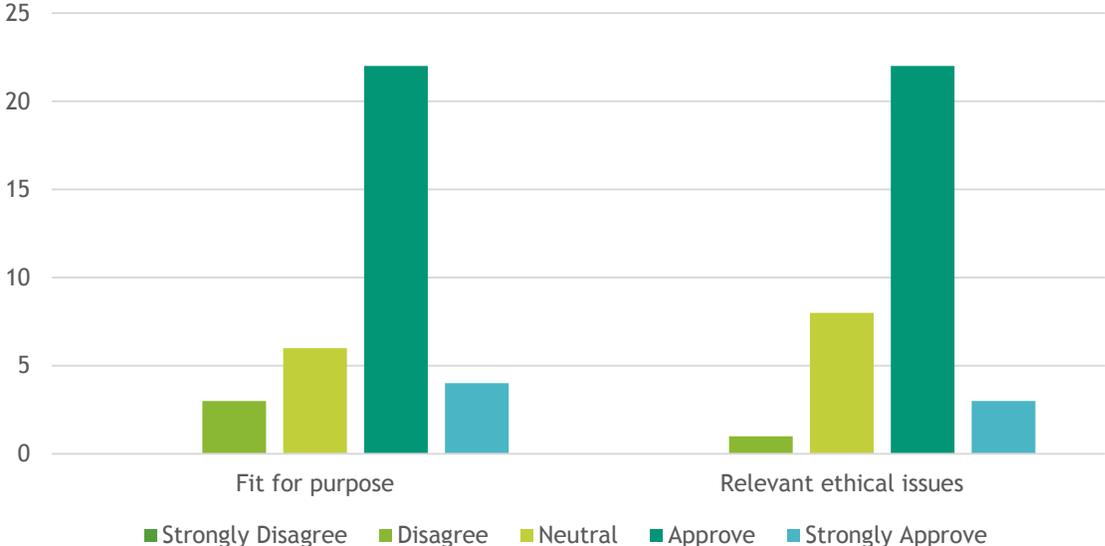
Fit for purpose

Feedback was positive overall for this section. Another explained that it was great to see linking back to whakapapa. One submitter felt there was an omission about approaching participants, as it needed to be flexible to provide guidance for different types of research recruitment (i.e. clinical trials, emergency or unplanned intensive care and observational research).

“A very good section for newer researchers.”

One submitter felt that the section should include more focus on independence, particularly with respect to review of trials by ethics committees and safety reviews, independence of members on a data monitoring committee, and more awareness of conflict of interest. As noted in other chapters and discussed in the high level themes, submitters made suggested changes to standards and commentary. One submitter noted social media also involves targeted advertising. Practical guidance was requested for cases such as disclosure of abuse and trauma.

Research conduct



Ethical coverage

One submitter described this as a comprehensive and thoughtful section. One submitter noted that open and transparent research should be highlighted in this section. The ethical tension between open publication and privacy was raised as an area for further guidance, as was re-iteration of the need for independent scrutiny of trials at approval stage and during the course of the trial.

General feedback

One submitter disagreed with the trial oversight table. Peer review was raised as an issue, with HDECs not conducting peer review, and only at the approval stage peer review is required. A respondent noted victim-blaming is applicable to other populations, such as LGBTIQ+ groups. The importance of registering clinical trials was raised. Clarification was sought for safety monitoring plans, and how this term was used across intervention studies and observational studies. A respondent drew attention to the need for health practitioners to be aware of conflicts of interests in their everyday role and in research. A few submitters disagreed with the claim that advertisements should not be “eye-catching”, noting advertisements should be eye-catching as it is their purpose.

Charging participants

The response to charging participants was mixed, with some taking a very strong view against allowing charging in New Zealand, and others being generally opposed.

“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.”

A similar number of submitters stated that the barrier was high enough and appropriate, and that they did not support a blanket ban. Others stated that they did not feel confident to comment on this.

“I rather like the high barrier. I am uninclined to make a blanket prohibition so a high barrier is the best option.”

Health data

Fit for purpose

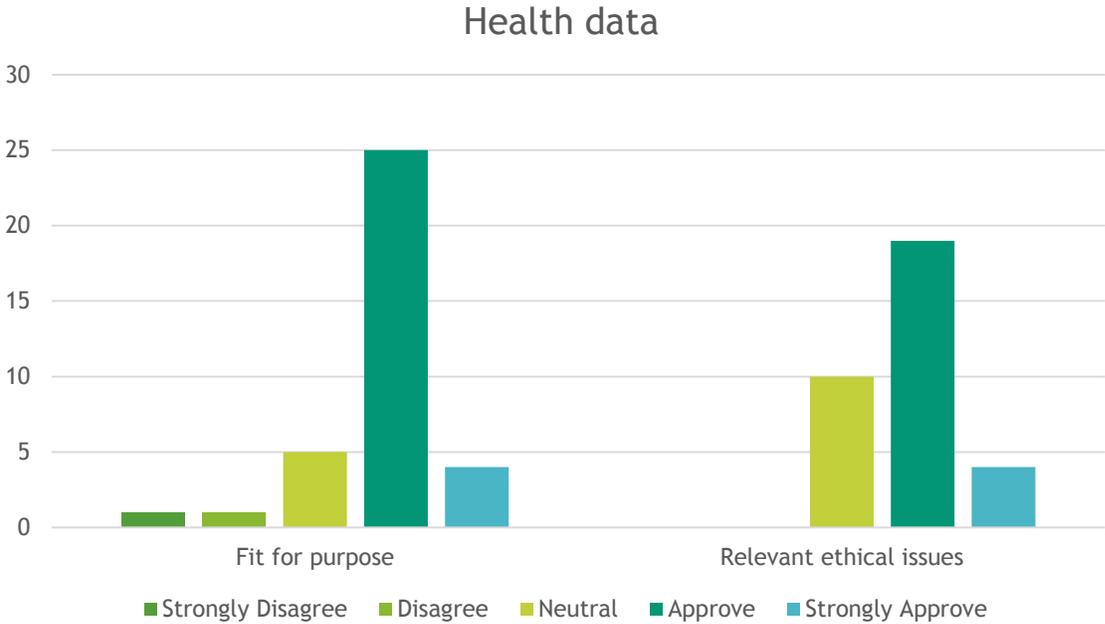
Many responses were positive about the health data chapter, noting the good overview of ethical issues associated with collection and secondary uses of data and recognising that it is a fast changing and complex area of research ethics. One submitter requested that guidance is provided to interoperate the ethical standards when using different types of data (identifiability for example). The levels of identifiability were commended by a number of submitters.

One submitter expressed the need to respect people’s rights to access their own data, and for communities to have data sovereignty, including benefits being extended to them.

Another submitter raised the importance of how the data was collected, and for what purpose, noting the difference between primary/specifically collected data and the use of existing health information data.

Submitters noted that data was assumed to be quantitative, rather than qualitative. There was a request for clarity about which standards applied generally compared to those for specific cases of data use, i.e. linking and the IDI.

The theme of structure relating to standards and commentary was expressed in this chapter, as outlined in the high level themes.



Ethical coverage

One submitter raised the need 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. One submitter recognised the tension between

utilitarian approaches and Kantian approaches to data ethics. One submitter noted that there is limited public disability data across a number of issues.

General feedback

Submitters raised a range of views on whether some, most or all data is taonga.

“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.”

It was suggested that cultural harms should be added in the data harms table. Feedback about the impact changes in data ethics would have on the ethics review systems in New Zealand was received. Registries required consideration in terms of their design. The issue of sending data overseas was raised by a number of submitters, and is an important issue to consider for the future.

“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”

Some new concepts such as social equipoise required further explanation.

Social media was also considered, for both recruitment and in terms of risks to scientific validity, if participants are discussing a trial they are participating in on social media. A few submitters requested definitions and clarifications on either new concepts or Māori terminology. The need to balance protections to privacy with safety considerations was raised. For example, removing identifiers from records of a person in a clinical trial exposed the participant to risk if they needed to identify a participant for safety reasons.

“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?”

The Health Information Privacy code must be included as referential regulation, and the waiver to use identifiable records needs to be more readily accessible in the standards.

Big Data

A submitter noted that people are becoming more aware of their data being used (inappropriately) through data leaks. Therefore it is good to have clear mechanisms in place for reusing and linking data. One submitter raised the question of how to prevent data being shared with commercial companies for commercial gain. Information in the commentary was suggested to be raised to the standard level, on individual and group harm and stigma – this is critical for Māori and Pacific peoples who have a long history of being statistically surveilled and of being the foci of victim-blaming deficit analyses.

The importance of ethical development and deployment of algorithms was raised.

“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.”

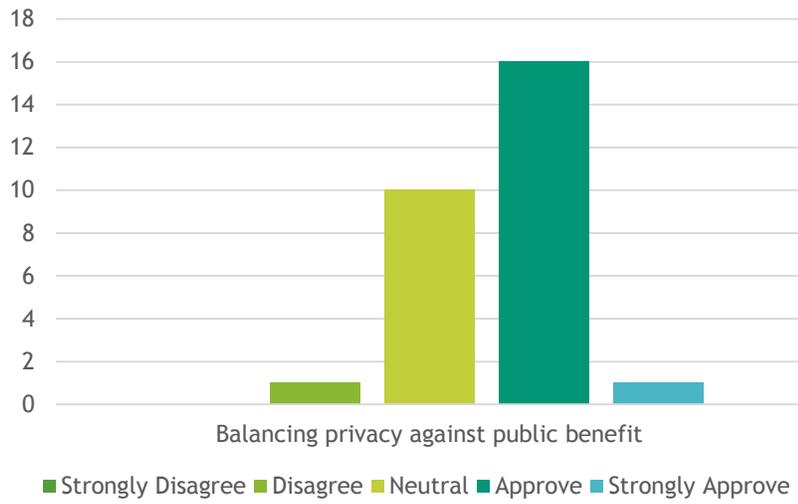
“Any application of computer algorithms to a particular task (including AI, whatever that means) needs to consider bias. Algorithms are imbued with the mauri and tikanga (or wairua?) of their programmers; when created without thought, they’re more likely to amplify inequities than correct them.”

Other submitters raised the question of how the IDI fit into these standards.

“One of the tensions not evident in the Commentary is that many researchers are now using linked data (such as in the IDI) from participants who often have not given explicit, informed consent for the secondary use of their data. However, because the data are de-identified for the purposes of analysis (although unique identifiers are used for deterministic linking) and are made available under the 5 Safes framework, issues of consent are glossed over.”

One submitter felt that the Standards do not provide enough information and discussion for researchers to consider the two opposing points (better use of data versus privacy), noting that the Standards have a higher weighting for efforts to protect privacy, and thereby limiting the optimal use of data.

Big Data



Data banks

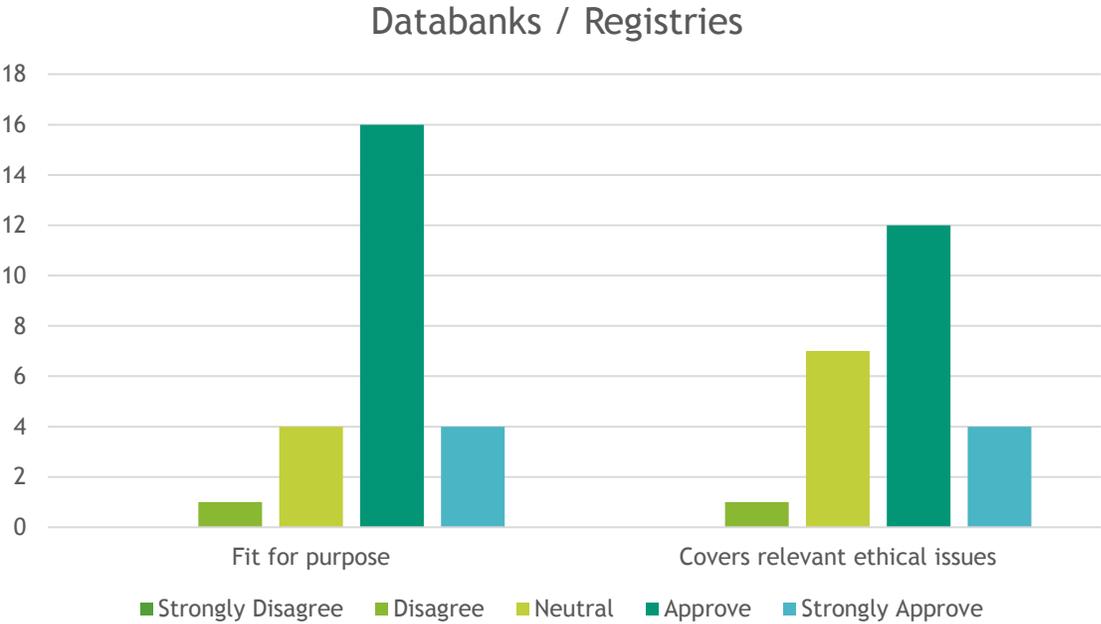
Fit for purpose

Submitters were mostly positive about the data banks section, noting it was clear, with one submitter thinking it actually gave more protection to data than the biobanks section did to tissue. Many submitters noted the importance of such a section, with some noting that it should be explicitly about registries as well. The relationship with health data and big data was recognized. One submitter noted that databanks were just one part of this data environment.

“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”.

Ethical coverage

Submitters queried if this section should explore the issue facing researchers where journals require more data to be shared. Another submitter raised the need to increase linking between databanks for research and quality improvement.



General feedback

Submitters explored some of the tensions with databanks, for example how it is possible to contact people who are in a registry without their consent. Another issue regarding secondary use of data, and how consent and the level of identifiability of the data being shared impacted ethics review and re-consent requirements. Balance was noted to be an issue, particularly when balancing the needs of the consumer with the needs of 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.”

Submitters also raised consideration about sharing nationally and internationally, and between different groups within New Zealand. Māori values were also discussed and suggested to be incorporated.

Human tissue

Fit for purpose

Submitters thought the section was generally fit for purpose. Guidance was said to be “forward-thinking and comprehensive,” though one person suggested the inclusion of a Pasifika position on tissue sampling, and another questioned what safeguards were in place to protect participants from the reporting of incorrect information. An area of concern for an additional submitter was the gene editing sub-section, which was seen not to adequately cover the use of gene editing technology on human cells other than embryos.

Issues of consent and identifiability were a common theme in the feedback. Submitters believed the standards should recognise that there are circumstances in which clinical safety should override ethical concerns over breach of data, so long as this eventuality is addressed in the information and consent forms. Further, greater clarity was requested on the sending of tissue overseas, consent for the use of a deceased person’s tissue, and on “current best practice.” Areas said to be lacking in guidance were the disposal of tissue and use of cadavers. Overall, submissions were of the opinion that the guidelines would benefit from flexibility and sensitivity to contextual issues which arise in the course of research on human tissue.

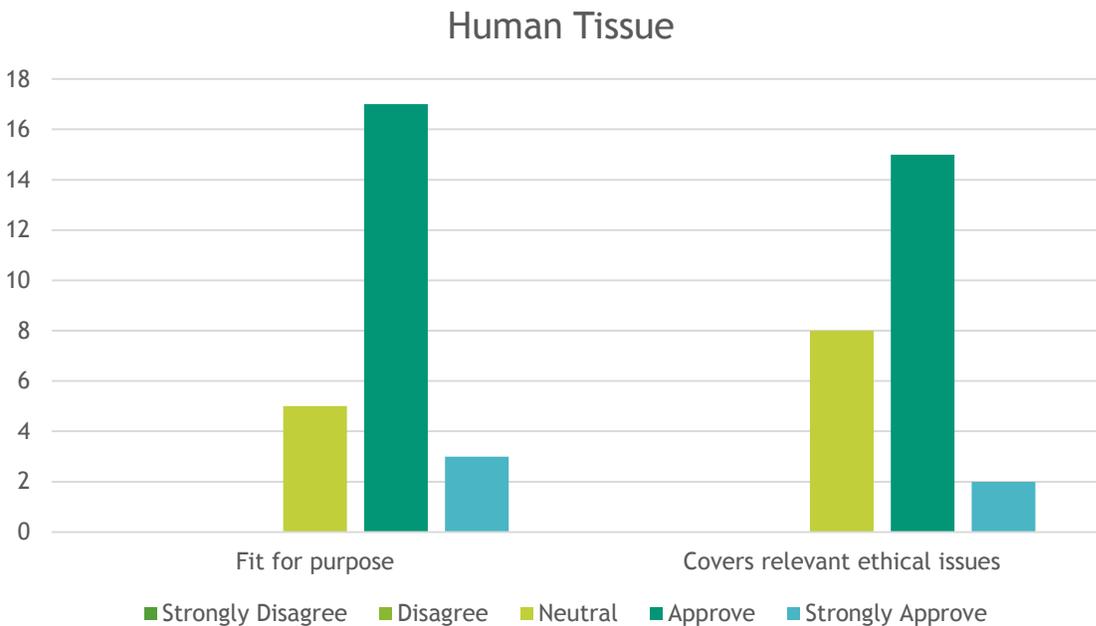
Ethical coverage

One submission suggested the inclusion of Māori values in this section, and greater discussion of the contextual risks involved in the use of different types of tissue was also advised.

The sub-section on genetics, which was seen as a “rapidly changing and ethically challenging” area, drew a significant response. Submitters suggested a ‘process approach’ rather than a distinct rule for providing findings to participants. Comments requested clarification on the terms ‘collective group’ and ‘genomic research’ in relation to Māori, and asked that the expectation of continued consultation be explicitly stated in section 15.44. Moreover, 15.39 should ensure that access to genetic and clinical advice and counselling is covered by the research plan, and there was a general consensus that geneticists and clinicians should be working in tandem. One person suggested that sections 15.35 and 15.39 relating to third party disclosure be amended, as they currently place too much responsibility on the part of the participant. The guidelines’ position on pharmacogenomics was also said to be absent here.

The proceeding sub-section on gene editing generated much discussion as well. 15.47, offering guidance for research on Māori embryos, was seen as too narrow and in need of addressing other ethnic and religious groups. Two submitters criticised paragraph 15.48 for its brief reference to the HART Act and

judged that its stance on gene editing could be stated in full.



General feedback

Regarding paragraph 15.1, two people thought the definition of human tissue should exist in the body of the text rather than as a footnote; of the definition itself another sought clarification on 'cell lines'. It was also thought that a mention of chapter 16 should be included.

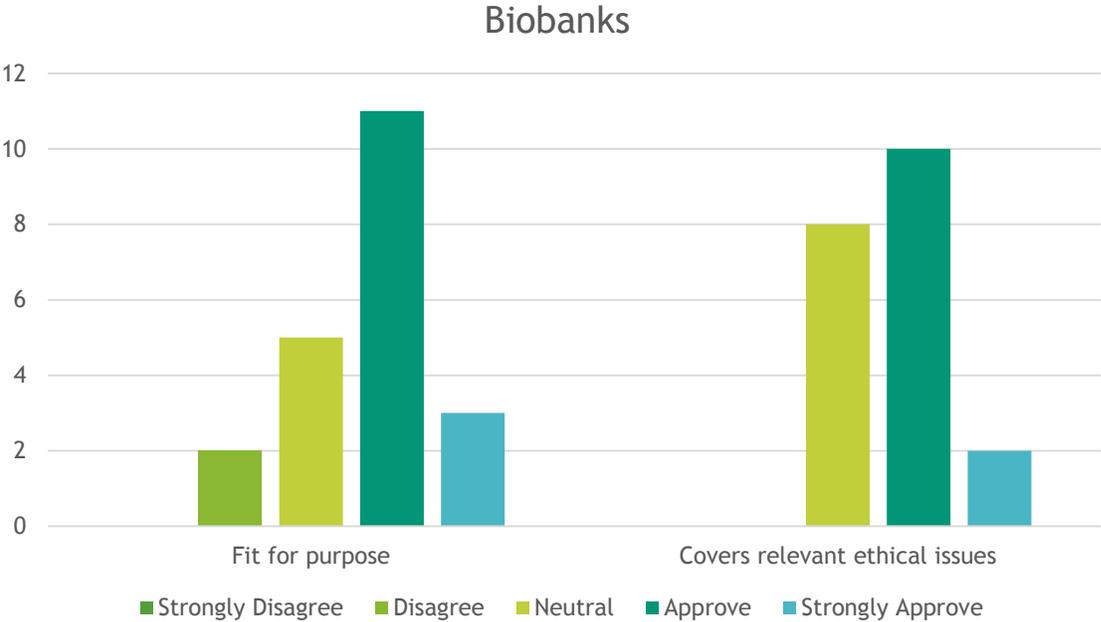
On 15.2 and its 15.25 commentary, submitters agreed that researchers have a responsibility to inform participants of incidental findings, but pointed out that the required 'counselling', itself a problematic and emotive term, would not be covered by a research budget. It was also noted however that informing participants of results may not always be consistent with the study plan.

Remaining feedback considered paragraph 15.15 inconsistent with 12.3, with multiple people stating that sections 15.21 and 15.26 are adequately covered by bio-banking guidance and not necessary here. One submitter judged issues relating to human tissue as perhaps complex enough to warrant individual guidelines, and another advised that GMO medicine is an emerging clinical option which is in need of inclusion.

Biobanks

Fit for purpose

Submitters thought the guidance in this section was broad and forward-thinking, with a lot of positive feedback directed at the coverage of participant consent in particular. One person thought this section largely fit for purpose, but suggested that national collaboration between biobanks needed addressing. The central theme of negative feedback, however, was the definition of ‘biobank’ itself. There was confusion as to whether any storage of human tissue whatsoever constitutes a biobank, or if biobanks are more complex in that they governed by a framework of use. In either outcome, submissions made clear that the current definition needs to be tightened. One submitter also asked for the standards to distinguish between biobanks for future unspecified research and those which arise in the course if a specific study.



Ethical coverage

Regarding sections on biobank governance, one submitter suggested the inclusion of details on the relevant ethics committees, going on to say that better governance could be guaranteed by a technical committee comprised of both science and ethics representatives. Another person, opposed to biobanking in general, advised that the participant’s right to withdraw their consent should be made clear. Also suggested by multiple people was better explanation of custodial arrangements. Additional comments indicated the absence of applied Māori principles and discussion of overseas biobanks.

Issues of informed consent and privacy drew the attention of submitters as well. One submitter thought the guidelines should make clear the difference between ownership of samples and ‘custodianship’, and should add more detail on types of consent. Problems with participants’ rights were identified by a number of people. Specifically, it was asked how participants will know if their information has been stored correctly, or how they will be made aware of their data being linked with other datasets. It was noted in one submission that participants may object to their samples being interfered with even if it is in the public interest, and that the guidelines could provide examples of this for the researcher’s reference. It was thought by one person

that tissue samples should never be made non-identifiable, and another requested that the conditions under which the stored tissue of a deceased donor can be transferred be clearly stated.

Additional feedback expressed uncertainty around who will enforce the proposed governance of tissue banks, and around who will be responsible, both operationally and financially, for independent audits of compliance for biobanks.

General feedback

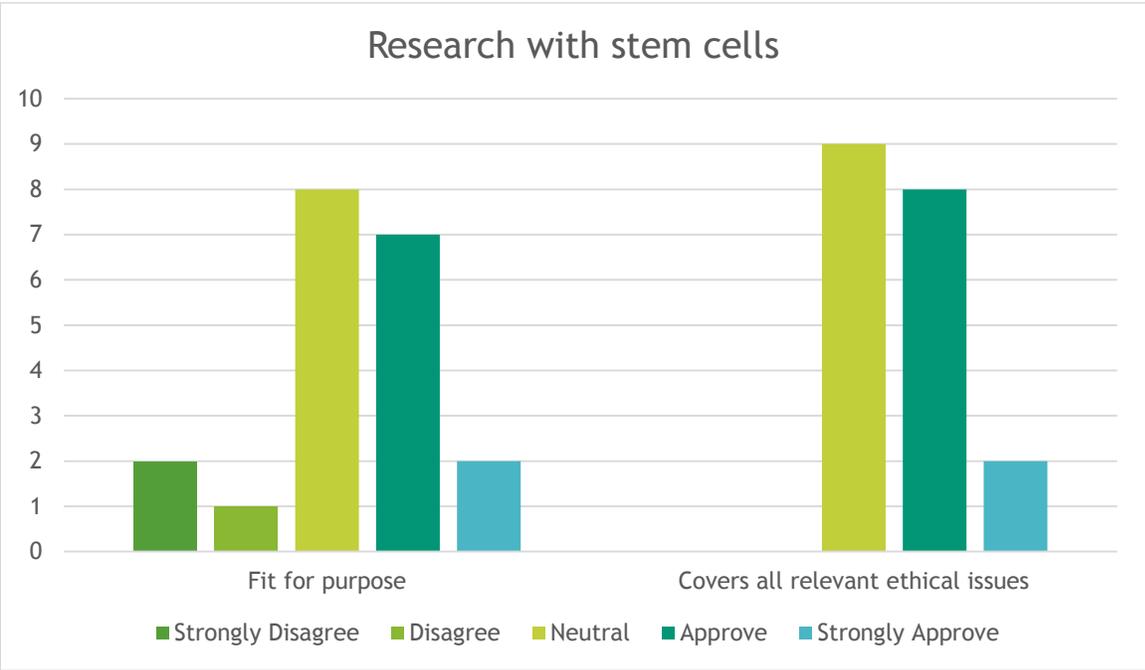
Responses to the biobanking 'Standards' sub-section suggested a number of changes and additions. One person was of the view that a change in the management structure of a biobank should void any existing consent attached to its samples. Regarding paragraph 16.8, two submitters requested changes; one thought that researchers and custodians should always deny and restrict biobank access when there is potential harm to participants, rather than simply considering it, and the other suggested linking this point to 16.27 where more detail to these harms is provided. Another submission agreed that researchers should justify the use of banked tissue beyond its initial purpose, but asked that the guidelines acknowledge that securing consent for extended use is not always feasible. The inclusion of a "close down basic plan" and the commercialisation of biobanks in the standards was also advised.

Research with stem cells

Fit for purpose

This section received significant feedback from two expert submitters, who noted the section needed a full overhaul. There were many helpful suggestions for improvement, ranging from minor changes to wording to amendments of whole sections for the Committee to discuss. Issues ranged from feasibility, technical concepts, practicality and, accuracy.

Further advice will be sought for this section to ensure it is technically accurate and ethically robust.



Compensation for commercially sponsored intervention studies

Fit for purpose

The section was commended by most submitters as being comparatively short and straight to the point.

There was general agreement 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. Most submitters agreed that compensation for injury must be at least the equivalent of ACC compensation that would be available to participants for non-commercially-sponsored research, but asked for further guidance on how to meet this requirement, specifically how to determine the level of compensation that is equivalent to ACC compensation so sponsors know what is being asked of them.

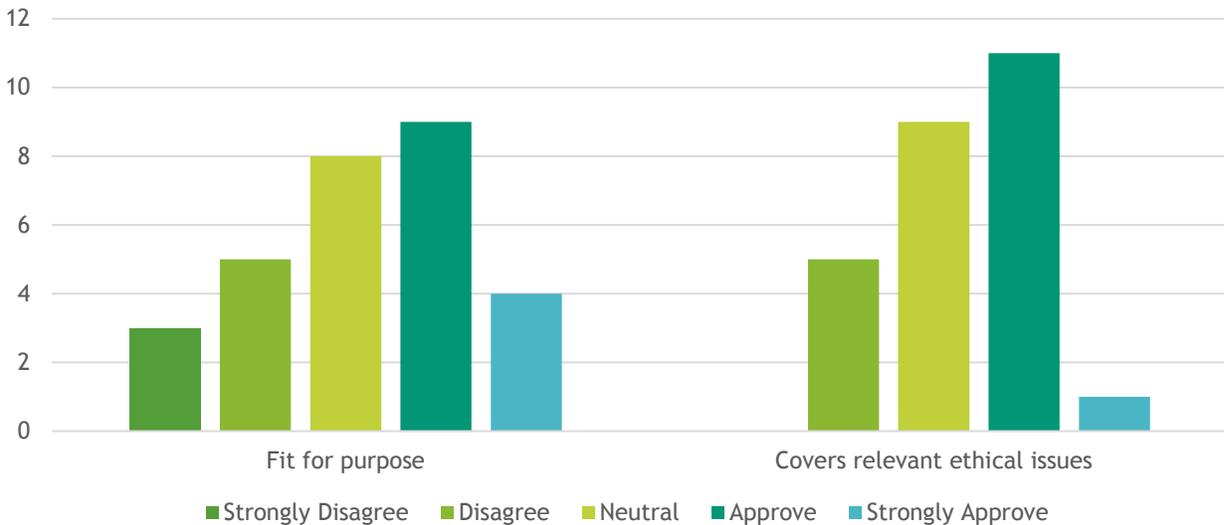
There was a suggestion from one submitter that this section links into the Informed Consent section, because 'What if I am harmed during the study?' is a standard section of a participant information sheet. While there was agreement among submitters that the draft Standards appeared to strengthen protections for participants, it was thought that they do not go far enough. Submitters stated that consumers need more protection in commercially sponsored research. Practical guidance was sought for determining what "ACC equivalent" means, as well as guidance for injury in studies that are not commercially sponsored, but are also not covered by ACC, such as emotional distress.

There was a strong theme that the current legal situation is not acceptable, and the best solutions would be to recommend: a) for ACC to extend its cover to clinical trials participants, or b) for sponsors to pay ACC levies in NZ to enable studies to be covered by ACC. Submitters also recognised that this would be outside of the scope of NEAC's role and would require a law change.

"I like this section; if there is commercial interest in research, those interests need to pay for the problems they cause."

"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."

Compensation for commercially sponsored intervention studies



Ethical coverage

Two submitters thought 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, might risk dis-incentivising commercial investment or New Zealand participants in clinical trials.

One submitter stated that they thought the standards appear to be based on an exaggerated view of the risks of needing to litigate to access compensation, because it is so rare in New Zealand.

One submitter thought that it is still not feasible to accurately convey risk and compensation arrangements under 18.7 by a member of a research team to potential participants in the setting of an informed consent discussion.

Generally, submitters still expressed unease about the situation and thought it was still not workable or adequate. Most submitters said that the best solution would be for ACC to extend its cover to clinical trials participants, however it was appreciated that this is beyond NEAC's scope.