



National Ethics Advisory Committee

Kāhui Matatika o te Motu

**Draft National Ethical Standards
for Health and Disability Research:
Consultation document**

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Introduction

The National Ethics Advisory Committee (NEAC) is an independent advisor to the Minister of Health. NEAC was established in 2001 by section 16 of the New Zealand Public Health and Disability Act 2000.

The National Ethics Advisory Committee's statutory functions are to:

- provide advice to the Minister of Health on ethical issues of national significance in respect of any health and disability matters (including research and health services)
- determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services.

In 2015 NEAC committed to a review of the 2012 Ethical Guidelines for Intervention Studies and Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities. In order to review the 2012 guidelines and develop new standards determined by NEAC, the Ministry of Health (the Ministry) established a Working Party to create a first draft.

This work was aligned with the Health Research Strategy 2017, which contained commitments to address investment and strengthening of health research in New Zealand, particularly with the focus of reducing inequity and improving health outcomes. The guidelines also form part of a general strengthening of the regulatory environment for health research, as the Therapeutic Products Bill recognises that ethics is an integral part of research conduct, resulting in protection and safety of participants in research.

The attached National Ethics Standards for Health and Disability Research (the Standards) draft set out the established ethical standards that apply to all health and disability research in New Zealand. The Standards are primarily targeted at individual researchers but they are also of use to ethics committees, research sponsors and for training and educating researchers.

NEAC has reviewed the draft Standards and seeks now the views and feedback of the public.

How to have your say

The consultation will be open until 5pm, 20 September 2018.

To take part in the consultation, please complete the online consultation at <https://consult.health.govt.nz/neac/national-ethics-standards> (Citizen Space).

If you cannot complete the consultation online please print out this document, write your submission and send it to:

NEAC Secretariat
Ministry of Health
PO Box 5013
Wellington 6011

There will also be public face to face meetings during the consultation. Please see <https://neac.health.govt.nz/> for meeting dates and venues.

If you have any questions, please contact us by email at neac@moh.govt.nz.

NEAC is seeking feedback on the following:

- **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 is aware of the complexity of ethical issues surrounding health and disability research. Therefore the consultation document provides the opportunity to provide detailed feedback on specific areas of the draft standards. As a submitter you are welcome to provide as much or little feedback as you want.

This consultation standards is sectioned into two parts.

The first is about the Standards as a whole, and asks questions about the new structure, the scope of the standards and whether they are complete. These are required to be completed.

The second part of the consultation is asks questions about each individual section (Ethical principles onwards).

You do not have to provide feedback on every section / chapter.

Each section has a set of standard questions, as well as some particular questions relevant to that section.

1 Introduction to the Standards

- 1.1 The *National Ethical Standards for Health and Disability Research* (“the standards”) are issued in line with the statutory functions of the National Advisory Committee on Health and Disability Support Services Ethics (the National Ethics Advisory Committee – Kāhui Matatika o te Motu, or NEAC). In particular, they help to ‘determine nationally consistent ethical standards across the health sector’¹
- 1.2 Health and disability research aims to generate knowledge about preventing and treating illness and disease, maintaining and improving health and wellbeing, and supporting people with disabilities to be included, participate more and be more independent. By conducting research according to ethical standards, researchers can generate such knowledge without violating the rights and interests of research participants.
- 1.3 These standards set out the ethical requirements that must be met or exceeded in order to comply with these standards when undertaking health and disability research and related activities, whether or not that research requires review by an ethics committee. The key objectives of the standards are to:
- safeguard the rights and interests of participants in research
 - promote high-quality ethical research for social, cultural and economic wellbeing
 - reflect the principles of the Treaty of Waitangi
 - foster awareness of ethical principles and practices among health care providers, researchers and the wider community
 - help researchers think through and take responsibility for the ethical issues in their studies
 - help researchers give due consideration to local and national community views and perspectives
 - protect and reassure the community.
- 1.4 The standards are primarily aimed at researchers, as researchers have the main responsibility for conducting ethical research. The standards are also of interest to others with a role or interest in health and disability research, including review bodies, industry, custodians, government departments and research participants (individuals and communities).
- 1.5 The standards in this document have drawn from statements in New Zealand and international ethical guidelines (see [‘References’](#) and [‘Helpful guidance’](#)). They do not provide detailed guidance on every possible research situation. Where other guidance and codes of practice are consistent with the *National Ethical Standards for Health and Disability Research*, researchers must refer to them for additional ethical guidance on how to meet the *National Ethical Standards for Health and Disability Research*.

¹ See section 16 of the New Zealand Public Health and Disability Act 2000.

- 1.6 Where they meet inconsistencies in their additional guidance, researchers must consider the *National Ethical Standards for Health and Disability Research* as the minimum to follow, however they may offer their participants a higher level of protection in accordance with the additional guidance as appropriate. Researchers are expected to be familiar with international and domestic ethical guidance materials relevant to their area of research (see 'Helpful guidance' for links to some of these resources).

2 Research in a New Zealand context

The Treaty of Waitangi and the standards

- 2.1 NEAC's statutory function is to 'determine nationally consistent ethical standards across the health sector and provide scrutiny for national health research and health services'.²
- 2.2 Both Māori, as the indigenous people of New Zealand, and the Crown are signatories to the Treaty of Waitangi, which sets the foundation for the people of New Zealand's enduring relationship as equal partners. The Government continues to respond to its obligations to honour the Treaty relationship. Māori seek to participate equally in their commitment to co-govern.
- 2.3 The three Treaty of Waitangi principles of partnership, participation and protection should inform the interface between Māori and research:
- Partnership working together with iwi, hapū, whānau and Māori communities to ensure Māori individual and collective rights are respected and protected.
 - Participation involving Māori in the design, governance, management, implementation and analysis of research, especially research involving Māori.
 - Protection actively protecting Māori individual and collective rights, Māori data, Māori culture, cultural concepts, values, norms, practices and language in the research process.
- 2.4 The Treaty partnership is an opportunity to design together an advanced national health and disability research ethics platform that encompasses two world ethical views: conventional ethics and tikanga Māori (indigenous ethics).
- 2.5 These *National Ethical Standards for Health and Disability Research* extend the work of previous committees. They now include specific Māori content and make more logical links between theory and practice. These standards are consistent with the strategic priorities of the New Zealand Health Research Strategy.³ The strategy contains four guiding principles for the health system: research excellence; transparency; partnership with Māori; and collaboration for impact.
- 2.6 These standards also recognise He Korowai Oranga the Māori Health Strategy⁴ (Ministry of Health, 2014) and the principles of Vision Mātauranga to:
- set priorities for Māori health research to seize opportunities for and address the challenges to Māori health and wellbeing
 - harness the innovation potential of Māori health knowledge, systems and processes
 - translate relevant findings into gains in health and social wellbeing for Māori
 - promote rangatiratanga
 - enable whānau, hapū, iwi and individual Māori to exercise control over their own health and wellbeing and the direction and shape of their own institutions.

² See Section 16 of the New Zealand Public Health and Disability Act 2000.

³ Ministry of Health. 2016. New Zealand health research strategy 2017–2027.

⁴ Ministry of Health. 2014. 'Ala Mo'ui: pathway to Pacific health and wellbeing.

- 2.7 Research excellence involves embracing and valuing a range of research approaches and methodologies that are fit for purpose and rigorous. Those approaches and methodologies must also meet the underlying need to conduct ethical research that keeps research participants safe, protects the privacy of individuals and respects the mana (status and authority) of families and whānau.

Strategic focus of health and disability research

- 2.8 Health and disability research in New Zealand will need to address the pressures that fall on our health system and to meet the needs of New Zealand populations. The New Zealand Health Research Strategy 2017–2027 and He Korowai Oranga the Māori Health Strategy, provide health and disability research in New Zealand with clear direction for addressing the health issues and needs of New Zealanders. Part of this work involves addressing inequality and inequity:

Health inequalities are the measurable differences in health status or in the way health determinants (factors that influence a person’s health, such as income, life expectancy, education and healthy housing) are distributed between different population groups.

Health inequities go beyond inequality in terms of differences in health determinants and in access to the resources needed to improve and maintain health or health outcomes. They also involve avoidable health inequalities caused by a failure to avoid or overcome unjust or unfair circumstances that lead to the inequalities that lead to unfairness and go against human rights norms. Some groups may require additional access to resources to address health inequities that arise from factors relating to, for example, ethnicity, disability, gender, age, low income, poor housing, rurality or lack of transport.

- 2.9 The New Zealand Health Research Strategy 2017–2027 has strategic priorities relating to research with Māori and Pacific peoples (Strategic Priority 1, Action 2, Action 3).
- 2.10 These standards contain specific chapters on Māori and Pacific health as these groups have recognised inequities in the health and disability system that high-quality health and disability research, among other actions, should help to address. As the New Zealand population is becoming more ethnically diverse, other ethnic populations and communities are also becoming an important focus for high-quality health and disability research. In research with specific population groups, researchers need to be mindful of the diversity in New Zealand and consider the views of those groups, which means they have to be sensitive and tailor their approaches to suit those groups.

3 Users' guide to these standards

Who these standards apply to

- 3.1 These ethical standards have been written to apply to all people undertaking health and disability research in New Zealand. This includes people undertaking health and disability research as part of government, industry, tertiary institutions, an organisation or a network of organisations, or as private individuals.
- 3.2 Each chapter contains standards that researchers must meet to conduct ethical health and disability research.
- 3.3 Individual chapters provide guidance on how to apply and interpret the standards under the heading 'Commentary'.

How to find information

- 3.4 You can click on any underlined blue words to go directly to further information.

Available online only

- 3.5 These standards are published online only and will be updated to ensure ethical standards remain relevant and accurate. Check the website⁵ to be sure you are accessing the current version.

Primary responsibility for meeting the standards

- 3.6 Researchers have the primary responsibility for identifying and addressing ethical issues in their research. When more than one researcher is involved in the research, the coordinating researcher has the overall responsibility for the ethics of the research.

Relationship between these standards and local review procedures

- 3.7 Ethics committees or research offices that may be considering a study will have their own procedures relating to review. The *National Ethical Standards for Health and Disability Research* have precedence over any standards or guidance that a review body issues, where the two sources of standards conflict in any way.

⁵ For further information please visit our website <https://neac.health.govt.nz/>

Complying with New Zealand legislation

- 3.8 These National Ethical Standards for Health and Disability Research are subject to legal constraints. While the standards may require researchers to conduct research to a higher standard than the law sets, they do not suggest that researchers may conduct research ethically or in compliance with these standards while failing to comply with the law. Where there is any inconsistency between the law and these standards, researchers must comply with the law. Researchers are responsible for meeting all relevant domestic legal requirements and international conventions when conducting research.
- 3.9 Legislation and conventions that may be relevant to those undertaking research include (but are not limited to) the:

Code of Health and Disability Services Consumers' Rights 1996

- Privacy Act 1993
- Health Information Privacy Code 1994
- New Zealand Bill of Rights Act 1990
- Human Tissue Act 2008 (particularly sections 9, 14, 19, 21, 22, 24 and 31)
- Care of Children Act 2004
- Health and Disability Commissioner Act 1994
- Health Practitioners Competence Assurance Act 2003
- Protection of Personal and Property Rights Act 1988
- Health and Disability Services (Safety) Act 2001
- Hazardous Substances and New Organisms Act 1996
- New Zealand Public Health and Disability Act 2000
- Accident Compensation Act 2001
- Treaty of Waitangi Act 1975
- Human Assisted Reproductive Technology Act 2004
- Medicines Act 1981
- United Nations Convention on the Rights of Persons with Disabilities 2006
- United Nations Declaration on the Rights of Indigenous People
- Declaration of Helsinki.

How the standards apply to New Zealand legislation

- 3.10 These standards are ethical standards to which every consumer has a right under Right 4(2) of the Code of Health and Disability Services Consumers' Rights 1996 (the Code of Rights). They are also applicable in relation to:
- 'clinical trials' for the purposes of the Accident Compensation Act 2001, section 32
 - 'medical or scientific experimentation' or 'medical treatment' for the purposes of the New Zealand Bill of Rights Act 1990, sections 10–11
 - 'human reproductive research' for the purposes of the Human Assisted Reproductive Technology Act 2004. The standards constitute 'applicable ethical standards' for the purposes of section 27(4) of this Act.

Feedback

- 3.11 If you wish to comment on your experience with using these standards, please contact neac@moh.govt.nz

General definitions

- 3.12 The following are some general definitions that apply across this document. See individual chapters for definitions of terms relevant to specific topics.

Conflict of interest

- 3.13 A conflict of interest occurs when professional judgement concerning one interest, such as a person's health or the validity of research, could be influenced by another interest, such as meeting recruitment targets, financial gain or impact on future career.

Custodian or Kaitiaki

- 3.14 Custodians or Kaitiaki are those individuals or groups responsible for protecting, monitoring the use of, and/or managing research data or samples, and are not limited to a particular research project; for example, a databank or biobank.

Ethics committee

- 3.15 An ethics committee is any committee that is responsible for ethically reviewing health and disability research proposals.

Funder

- 3.16 A funder is an individual, company, institution or organisation that provides funding for a study but does not have responsibility for initiating or managing the project.

Māori terms – words in te reo Māori

- 3.17 Please view <https://maoridictionary.co.nz/> for definitions of Māori words.

Participants

- 3.18 Participants are people who are enrolled in studies. In some studies, participants are grouped in communities (eg, geographical communities or organisations such as schools). Other studies may use participants' data or tissue.

Researcher and coordinating researcher

- 3.19 A researcher is any individual who is involved in the research design and/or who conducts all or part of a study.
- 3.20 A coordinating researcher (often also termed principal investigator) is the qualified health professional or researcher with primary responsibility for conducting a particular study in New Zealand.

Should versus must

- 3.21 Both 'should' and 'must' are similar in meaning except that "must" is a much stronger word as compared to 'should'. 'Must' 'means that the standard is the minimal or bottom-line standard and must be met in order to comply with these standards. Any exceptions to the standard are clearly detailed, and in most cases require a justification

Sponsor

- 3.22 A sponsor is an individual, company, institution or organisation that is responsible for initiating, managing and/or financing a study.

4 Scope of the standards

- 4.1 These standards set out the ethical requirements that researchers must meet or exceed when undertaking health and disability research in New Zealand. They apply whether or not that research requires review by an ethics committee.

Defining the boundaries of health and disability research

- 4.2 It is not easy to offer a simple definition of research, or to provide a clear line between activities that are research and activities that are not.
- 4.3 See the box for a broad description of research.

For the purposes of this document, health and disability research aims to generate knowledge to:

- prevent, identify and treat illness and disease
- maintain and improve health – meaning health as a state of physical, mental, spiritual and social wellbeing rather than simply the absence of disease or infirmity
- support people with disabilities to be included, participate more and be more independent
- address disparities
- contribute to whānau ora.

This definition is necessarily broad because we acknowledge that people's health is part of a much wider range of social factors than their health care.

More specifically, health and disability research is any social science, kaupapa Māori methodology, or biomedical, behavioural or epidemiological activity that involves systematically collecting or analysing data to generate new knowledge; in which human beings are exposed to manipulation, intervention, observation or other interaction with researchers either directly or by changing their environment, or that involves collecting, preparing or using biological material or medical or other data to generate new knowledge.

- 4.4 One of the reasons why providing a clear, simple definition of research is impossible is that a range of activities fall in a grey zone between obvious examples of research and ordinary clinical and related activities such as diagnosis that are clearly not research. The classic example is clinical audit. The next box lists other activities, which vary widely in form, that are considered non-research.

Applying the standards to relevant non-research practices

- 4.5 These standards are specifically aimed at researchers who are conducting health research. However, from an ethical point of view, the principles and the standards apply to all practices where they are relevant.

4.6 Regardless of how a study is categorised and whether it falls formally within the scope of these standards, people involved in activities that share features of research should follow these standards. For example, quality assurance projects, while not categorised as research, involve accessing and using health information, so ethical considerations of confidentiality and privacy will apply. Another example is when a programme evaluation involves patients providing feedback, those conducting the evaluation must respect these patients even though the activity is not categorised as research. Finally, projects that are not research must still be methodologically sound and have merit.

The following activities, in line with international guidance, are considered non-research.

Some activities may start as a non-research activity, but then develop a research component. In such cases those involved in the activity must reconsider whether further ethical oversight is warranted.

- Public health investigations explore possible risks to public health, are often immediate or urgent and are often required by legislation. Examples are investigations into outbreaks or clusters of disease, analyses of vaccine safety and effectiveness, and contact tracing of communicable conditions.
- Public health surveillance involves monitoring risks to health by methods that include systematically collecting, analysing and communicating information about disease rates.
- Pharmacovigilance (post-marketing surveillance) involves monitoring the adverse effects of pharmaceuticals after their introduction into the general population. Its methods include spontaneously reporting adverse events and monitoring all adverse events for a restricted group of medicines (prescription event monitoring).
- Resource utilisation reviews evaluate the use of resources in a particular health or disability service activity. For example, they might review health records to determine health care inputs such as chest X-rays for patients with a particular diagnosis.
- Programme evaluation focuses on a whole programme, rather than specific interventions, where the sole purpose of the exercise is to refine and improve the programme or monitoring.
- Audit and quality assurance activities involve investigating whether an activity meets explicit standards, as defined in an auditing document, for the purpose of checking and improving the activity audited. An audit generates knowledge for the situation in which it was collected rather than generalisable knowledge. It should provide feedback primarily to the service, although it may also involve a more general publication or presentation of its findings. Access to confidential medical and personal information the service holds should be restricted to those individuals the service provider employs or contracts, the funder of the service, or an agency responsible for overseeing the safety and quality of the service. Such information should be used solely for the purpose of auditing a service.
- Quality improvement involves cycles of interventions that are linked to measurable assessment with the goal of improving the process, outcome and efficiency of health care. For an activity to be considered quality improvement, it must not be conducted to generate evidence to support an intervention's efficacy, but it can involve evaluating and changing practice.

Innovative practice

- 4.7 An innovative practice involves the provision of a clinical intervention (diagnostic, therapeutic or prophylactic), be it a therapeutic drug, medical device or clinical procedure, that is untested, unproven or not in common use and therefore poses its own unique set of characteristics and issues.⁶
- 4.8 The overall goal of any innovative practice is either to provide some immediate treatment in relation to an individual consumer or consumer group concerned, or to create new efficiencies in practices that will benefit consumers on a more general basis.
- 4.9 Health care must always be tailored to the individual needs, circumstances and medical condition(s) of each consumer. It is therefore not unexpected that the care of individual patients may vary around a core of standard accepted practice. Another aspect that must be recognised, is that what may constitute accepted practice for one body of health practitioners may well be considered innovative by another. Exactly what constitutes innovative practice is, therefore, a difficult concept to define in absolute terms.
- 4.10 Often new techniques or procedures may result from unplanned responses to medical complications arising from the treatment of an individual consumer. Health professionals must also be allowed to make minor deviations from accepted practice to adjust health care to suit the individual needs of each consumer. It must also be recognised that a series of small incremental changes to accepted practice may eventually result in a significant shift from accepted practice. It is therefore important that all health interventions follow the principles of best clinical practice.
- 4.11 In general terms an innovative practice may be considered to be a planned deviation from the currently accepted practice of a New Zealand body of health professionals involving an untested or unproven clinical intervention intended to be used on an ongoing basis.
- 4.12 Innovative practice includes the application of known procedures in new or novel circumstances in which they have not previously been tested. It may involve new delivery practices by health practitioners, new devices, new investigative procedures, or clinical management options.
- 4.13 Innovative practice must only be undertaken by health practitioners with appropriate qualifications and expertise and for the purpose of treating a specific medical condition of an individual consumer or consumer group.
- 4.14 Appropriate safeguards should be in place to ensure that independent clinical assessment occurs through the treatment process so that, should it become apparent the innovative practice is not achieving positive results or is exposing consumers to unnecessary harm, consumers can be shifted to standard treatment protocols.
- 4.15 Innovative practice must not be prematurely adopted into standard of care. Appropriate evaluative mechanisms should be put in place to assess the effectiveness of any innovative practice, which may include formal research.

⁶ Ministry of Health. 2008. Standard operating procedures for Health and Disability Ethics Committees.

Research into innovative practice

- 4.16 Where innovative practice in health care requires research, it is an obligation of those practicing innovatively to ensure this happens at the appropriate time and in the appropriate way.
- 4.17 Research into innovative practice must meet the ethical standards in these Guidelines, including the requirement for ethical review.

When innovative practice requires research

- 4.18 A challenge is identifying when difference from existing practice requires research, when the time has come formally to research an innovative practice, and what the nature of the research should be.
- 4.19 Some considerations that may suggest that Innovative practice requires research is when:
- the practice in question represents more than a minor variation on existing practice or is a new practice
 - the outcomes of the innovative practice are unknown
 - the innovative practice represents a considerable or great degree of risk
 - the innovative practice represents a test of a theory (or, even more informal, a hunch)
 - the innovative practice is premeditated.
- 4.20 It may not be required to conduct full research on minor innovations.

Good practice in innovation

- 4.21 Where innovative practice does not meet the criteria for needing research, innovators still have ethical obligations related to the newness of the practice. For example, fully informed consent to the use of innovative surgical techniques or devices is required. A recognised danger in this space is that the practitioner – and the patient – may believe that what is new is necessarily better than current practice. However, this belief may not be well founded, and this has to be made clear to the patient. To reduce the risk of false belief, the innovator may not be the best person to try to get consent.
- 4.22 In addition to this, good records of the nature of the innovation, of the outcomes of its use for the patients, and of developments and refinements, is vital. New techniques and other innovations should be clearly described, and registered, enabling innovators to see if their ideas have already been tried elsewhere. A similar level of openness may be difficult to achieve in a more commercial setting, such as medical device manufacture; and the commercial imperative (eg, commercial sensitivity) may triumph over the ethical imperative.

5 Ethical principles

Introduction

- 5.1 The Treaty of Waitangi established the constitutional foundation for New Zealand. Its articles are often represented through the principles of partnership, participation and protection. In the context of health and disability ethics, the principle of partnership includes the ethical partnership represented by both Te Ara Tika principles and the bioethics principles.
- 5.2 Te Ara Tika, meaning to ‘follow the right path’, is the name given to the guidelines for Māori research ethics).⁷ Te Ara Tika principles are used in this document to represent a generic set of principles commonly shared by many generations and communities of Māori, and can be seen to apply to all people in Aotearoa New Zealand.
- 5.3 The bioethics principles are widely recognised. They have been used in many sets of human research ethics guidelines, which have carefully established and developed their implications.
- 5.4 The principles presented in this chapter represent the ethical sources of the more specific ‘musts’ and ‘shoulds’ of the detailed standards in the chapters that follow.

Reasons for choosing the term ‘principles’

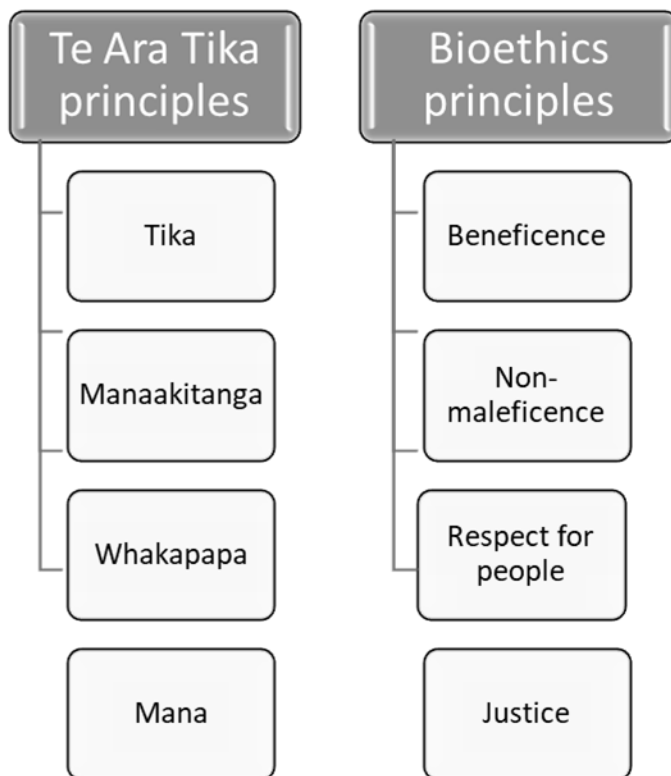
- 5.5 The term ‘principles’ has been chosen because this implies a role in guiding action, as well as being something foundational. It is a commonly chosen term among similar sets of standards internationally and was the term chosen for Te Ara Tika.

The principles

- 5.6 Figure 1 summarises the two sets of principles under the broad categories of Te Ara Tika and the bioethics principles. The discussion that follows explains each principle in more detail.

⁷ See Hudson et al. 2010. Te Ara Tika Guidelines for Maori research ethics: A framework for researchers and ethics committee members.

Figure 1: Overview of Te Ara Tika and bioethics principles



Te Ara Tika principles

5.7 Te Ara Tika principles are tika, manaakitanga, whakapapa and mana.

Tika

Tika refers to what is right and what is good for any particular situation. It relates to the design of a study and whether the research achieves proposed outcomes, benefits participants and communities and brings about positive change.

Tika requires respectful relationships with Māori and mana whenua in all studies, regardless of the research design and methods.

Manaakitanga

Manaakitanga refers to caring for others, nurturing relationships and being careful in the way others are treated. Aroha (respect, love), generosity, sharing and hosting are essential parts of manaakitanga, as is upholding the mana of all parties.

Manaakitanga relates to cultural and social responsibility and respect for people. This value requires an understanding of the appropriateness of privacy and confidentiality to safeguard any harmful effects from disclosure of information, the importance of collective participation in establishing the goals and benefits of a research proposal, and empowering research partnerships.

Researchers are expected to learn as well as gather data in research, to collaborate and to give back to the community (eg, through koha and sharing ideas).

Whakapapa

Whakapapa refers to the quality of relationships that are developed, why these relationships have been formed and the structures or processes that have been established to support these relationships.

Whakapapa relates to the quality of any consultation or engagement process with Māori and monitoring the progression of relationships through various stages of the research, from beginning to end.

The relationship between researchers and participants (and New Zealand communities) must involve trust, respect and integrity.

Mana

Mana refers to power, prestige, leadership and authority bestowed, gained or inherited individually and collectively. It can influence the balance and management of leadership, interpersonal and inter-group relationships so that research shares knowledge and upholds the mana of participants.

Mana relates to equity and distributive justice in terms of the potential or actual risks, benefits and outcomes of research. It also acknowledges issues of power and authority in relation to who has rights, roles and responsibilities when considering such risks, benefits and research outcomes. Finally, mana requires that the research process upholds appropriate aspects of tikanga Māori and respects local protocols.

Bioethics principles

5.8 The bioethics principles are respect for people, beneficence, non-maleficence and justice.

Respect for people

Respect for people underlies the principle of respect for autonomy. Respecting a person's autonomy means giving due regard to a person's judgement in making decisions – for example, about whether to participate in research. An important mechanism for respecting participants' autonomy in research is for researchers to seek their free, informed and ongoing consent.

Autonomy may be affected by a person's capacity to make an informed choice or give informed consent. Capacity can change over time, and depend on the nature of the decision and any changes in a person's condition. Diminished capacity may be permanent or temporary.

Where a person is not able to make a decision for themselves, even after support has been offered, then further measures are necessary to protect their interests and respect their wishes.

Beneficence

Beneficence for individuals and communities implies improving or benefiting health or broader wellbeing. It is both the basic aim of good research and its fundamental justification.

What counts as a benefit may differ between individuals and communities. Researchers should take different views into account through mechanisms such as informed consent or community agreement where that is appropriate.

Non-maleficence

Non-maleficence requires researchers to avoid causing harm to individuals and communities. The risks of harm in research should not be greater than its expected benefits.

Individuals that choose to participate in research should be fully informed of potential harms, both to them individually and to any community to which they belong.

At a community level, potential harms may place an inequitable burden on a community without providing a compensating benefit.

Researchers must put appropriate measures in place to reduce the [risk of harm](#) and effectively respond to any harm to individuals and communities.

Justice

Justice requires that people are treated fairly and equitably. This includes fairly distributing or balancing the benefits and burdens of a study to populations and individual participants.

Justice also involves reducing inequities and unjust inequalities in health outcomes for specific groups such as socioeconomic or ethnic groups. When researchers are determining research questions and processes, they should consider how the research could reduce inequities in health and wellbeing.

A partnership of principles

- 5.9 These standards do not give ethical or conceptual priority to either the principles of Te Ara Tika or traditional bioethics. No assumption is made that they cover the same ground in all cases, but an important common ground for them is that they involve knowledge discovery through respectful and rights-based engagement between researchers, participants and communities to advance health and wellbeing.
- 5.10 These principles are the ethical sources of the more specific standards set out in the following chapters. For example, the ethical demand that participants give their informed consent to participate comes from the principle of respect for autonomy, which can in turn be justified by the principles of mana and manaakitanga and/or by the principle of respect for people.

- 5.11 When they are described in the abstract, away from a specific context, as this chapter has done, all the principles are equally and supremely important. But in any particular context, it may not be possible to realise them all in actions because they may make incompatible demands on researchers. For example, the demands of mana, manaakitanga and respect for people may support the demand for individual informed consent; but it may not be possible to meet the demand to do good by improving health outcomes (tika, beneficence) if informed consent is required, for example when studies involve linking large data sets.

6 Research involving Māori

Introduction

- 6.1 Māori are the indigenous people of New Zealand. The recognition of indigenous rights has been a key driver for developing frameworks, declarations and guidelines on ethical research practice. These documents emphasise self-determination for indigenous peoples; the protection of heritage, indigenous knowledge, plants and genetic material; and the right to ‘maintain and strengthen their distinct political, economic, social and cultural characteristics’. These rights are included in the World Health Organization’s guidance on indigenous peoples and participatory health research, a range of United Nations conventions and guidelines on the rights of indigenous peoples, as well as the Mataatua Declaration.⁸
- 6.2 The rights of indigenous people in New Zealand, or tāngata whenua, are the rights to:
- self-determination
 - equity of values
 - collective wellbeing
 - equal quality of information
 - policy based on evidence that is valid for Māori.

Standards

- 6.3 Research design must demonstrate cultural rigour in order to meet ethical requirements.
- 6.4 Researchers should operate with cultural rigour, which includes considering what cultural concepts, norms, practices and language are important in the research process, and actively protecting Māori individual and collective rights.
- 6.5 Researchers must act with integrity and transparency when conducting research involving Māori. When they are conducting a study with a particular whānau, hapū, iwi, community or organisation, the consultation process should form part of gaining agreement for the research proposal.
- 6.6 All researchers must clearly identify the Māori collective (whānau, hapū, iwi) or the Māori stakeholder grouping (eg, Māori with diabetes, young Māori mothers) they wish to engage in research.
- 6.7 Researchers must collect ethnicity data, unless there is a valid justification why it is not necessary.

⁸ For more information on the Mataatua Declaration on cultural and Intellectual Property Rights of Indigenous Peoples please visit www.wipo.int/export/sites/www/tk/en/databases/creative_heritage/docs/mataatua.pdf.

Commentary

The importance of health research with Māori

- 6.8 Health inequalities are differences in health status or in the way health determinants are distributed between different population groups. Inequalities are the measurable component of difference. Health inequities go beyond inequality in terms of differences in health determinants and access to the resources needed to improve and maintain health or health outcomes. They also involve a failure to avoid or overcome inequalities that lead to unfairness and go against human rights norms.
- 6.9 There are significant inequalities in health status between Māori and non-Māori. Some of the reasons for these inequalities are that the two population groups differ in their:
- access to the determinants of good health (such as economic security, good-quality housing, safe and secure employment, good-quality education and freedom from racial discrimination)
 - access to health and disability services
 - quality of care received.
- 6.10 These persistent and significant health inequities between Māori and other New Zealanders have been described as an ongoing breach of the Treaty of Waitangi and as avoidable, unethical and unjust. This is a further argument supporting a focus on Māori health aspirations in the ethical review of all health research.

Engaging and consulting early

- 6.11 All research in New Zealand is of interest to Māori: every study can offer a training opportunity for a Māori researcher; every study may carry risks or produce benefits for Māori; and all research has the potential to help Māori achieve their aspirations. Every study in New Zealand therefore should consider the degree to which it can contribute to Māori health outcomes.
- 6.12 Consultation is expected for all health research. However, in practice researchers often conduct it after they have set their research protocols. Engagement with Māori at an early stage in the design of the study is preferred, particularly for research involving Māori. Early engagement allows Māori to participate in discussions about the research question, governance and conduct, as well as about the analysis and implementation of research findings.
- 6.13 Researchers need to answer certain questions right from the start, such as:
- What might this research offer to Maori communities?
 - What questions should the research try to answer to improve wellbeing of Maori communities?
 - What methods are best to use and should be used to conduct research with Maori communities?

- 6.14 Māori participation in research is important and researchers should facilitate it. Researchers should develop relationships with Māori that are effective, appropriate and meaningful, with an equal balance of power. A process of consultation with Māori will be inadequate if those consulted play no part in framing the research question or if their opinions are not reflected in the analysis and research outcome. Instead, meaningful engagement with Māori involves their active participation, with Māori values and views evident throughout the research process.
- 6.15 Researchers must carefully consider who it is best to engage with so that those involved have sufficient knowledge to play a meaningful role. Tika and mana are important Māori values. To practise those values, researchers must give Māori adequate opportunity and appropriate resources (including time) to become familiar with the processes, prospects, risks and benefits of the research proposal.
- 6.16 Meaningful engagement is often the first step to developing a long-term relationship with the community beyond the life of the study.

Consultation

- 6.17 Consultation supports researchers in establishing cultural sensitivity and understanding.
- 6.18 While matters of culture are important in the research process, researchers also need to consider conceptual issues and questions, along with the shape of research outputs. In this way, the results from health research can contribute more strongly to the health status of Māori.
- 6.19 In the case of international clinical trials it will often be the case that the protocol is designed overseas and is being applied to a New Zealand context. In such cases it is important to try to adapt the protocol to the New Zealand context as much as possible.

Degrees of consultation

- 6.20 Different levels of Māori involvement, and different research topics, may differ in the level of consultation they require. The following examples of Māori involvement in research move from the lowest to the highest level of involvement. At each level is a corresponding need to engage with Māori.⁹

⁹ See Hudson et al. 2010. Te Ara Tika Guidelines for Māori research ethics: A framework for researchers and ethics committee members for what each level of consultation involves and questions that should be considered.

Box 1: Varying levels of consultation with Māori across different types of research

Research not involving Māori does not seek Māori participation or data and the results are thought to have no direct relevance to Māori health.

Minimum expectation: Institutional review that confirms that exclusion of Maori is valid and justified.

Research involving Māori may involve Māori as individuals or collective participants, Māori data or researchers, or the outcomes of the study are of relevance for Māori. Māori are included as part of general population research.

Minimum expectations:

- Institutional Ethics approval confirms the design, methods and analysis is appropriate for Maori as individuals and the collective/s
- Maori ethnicity data can be extrapolated from a general sample.
- If collectivises are involved:
 - Researchers are clear on the specific Maori collective/community of interest for their research.
 - Consultation with the collective occurs at the earliest stages of development of the research design
 - Collective consent is obtained from the appropriate mandated leadership/governance entity for the named collective. For example, consent for iwi research would be endorsed or approved by the iwi governance organisation/s. In some cases there may be more than one governance group.

Māori-centred research usually involves Māori at all levels. The focus of the study is on Māori: the methodology and analysis are appropriate for Māori, and research questions are concerned with outcomes for Māori. The study may use western methodologies but will expect a higher level of cultural integrity and practice. This type of research often has dual accountability – to both non-Māori (often an institutional body such as a university) and Māori – although commonly the knowledge outcomes are measured against non-Māori research standards and methodologies.

Minimum expectations: As above.

Kaupapa Māori research has been defined as ‘research by Māori, for Māori and with Māori’. It is grounded in Māori tradition, legitimises Māori knowledge, is controlled by Māori and is accountable to Māori expectations and quality standards. The nature of kaupapa Māori research allows researchers to use a broad range of research methodologies to fulfil such objectives.

Minimum expectations: Research is led by Maori and addresses issues of importance to Maori using Maori methods of conduct and analysis. All of the above expectations would also apply.

Sharing benefits with Māori

- 6.21 Manaakitanga and mana are the principles that underpin sharing the benefits of research. When researchers are considering their research in terms of its ethics, part of this task is to understand the nature of the range of outcomes from that research (risk versus benefit; short versus long term) and how those outcomes will be distributed (among researchers, participants, communities and society). Researchers will benefit from their involvement in research but they should also consider the potential benefits for Māori participants and their communities.
- 6.22 When considering how Māori can benefit from their research, researchers should review the incidence and prevalence (statistics) of the disorder under study (or treatment indication if it is a drug trial) in Māori. Most disorders are particularly important for Māori health, while a very few are relatively rare in Māori and may have less of an impact on them. Although prevalence is an important factor, some disorders may have the same or a low prevalence, but worse outcomes for Māori. Researchers should also consider health outcomes. Generally, they should consider any available statistics relating to Māori when designing research. Researchers must be honest and open about all parts of their research, including their publication plans and how they will personally benefit from undertaking the research.
- 6.23 If the research has an impact on Māori health, the protocol should include information on how researchers will ensure that Māori benefit at least equally (and actually how they can gain greater benefit than the general population if a higher proportion of participants are Māori). For example, what extra measures, if any, are in place to ensure Māori participate (eg, iwi consultation, Māori researchers, active follow-up) as well as to involve them in interpreting results or study findings, and to feedback findings to those consulted in an appropriate way? (See also [Table 2](#) on benefit sharing in Chapter 10.)

Ethnicity data collection

- 6.24 New Zealand is recognised as a world leader in its ability to analyse health data by ethnicity. Good-quality ethnicity data must be collected in all health research conducted in New Zealand. Health research helps to track the growing diversity of the population and to provide more detailed information for planning, funding and monitoring health services.
- 6.25 The process of collecting and reporting ethnicity data in New Zealand has evolved significantly over time. New Ethnicity Protocols, released October 2017, are a standard of the Health Information Standards Organisation that cover research.¹⁰
- 6.26 In some cases (eg, small studies with specific population groups), it may not be necessary to collect ethnicity data. However, it is good practice to include ethnicity as a variable as part of any demographic data. See the section on [equal explanatory power](#) in Chapter 11.
- 6.27 An important step in addressing inequalities and achieving health equity is to identify inequalities by consistently collecting good-quality ethnicity data. Such data can be a source of comparative data and can influence the outcome and recommendations of research. It can also support research in its contribution to improving Māori health outcomes and reducing inequities.

¹⁰ For more information on the new Ethnicity Protocols please visit: www.health.govt.nz/publication/hiso-100012017-ethnicity-data-protocols.

7 Research involving Pacific peoples

Introduction

- 7.1 The term ‘Pacific peoples’ does not refer to one homogeneous group of people. Rather, it describes a distinctive range of cultures, heritages, languages and diverse communities whose ethnic heritage and cultures come from Polynesia, Micronesia and Melanesia. The diversity can be both ethnic and national and includes people born in the Pacific Islands region and those of Pacific heritage who are born in New Zealand. While these standards use the term ‘Pacific peoples’, the terms ‘Pasefika’ and ‘Pasifika’ are also used in Aotearoa New Zealand.
- 7.2 Pacific communities have a holistic perspective of health and wellbeing. This includes an interconnectedness between beliefs and values, as well as between cultural, emotional and social dimensions, and a view that health and wellbeing are often influenced by family and community, specifically in relation to health and illness.
- 7.3 Pacific health research creates knowledge essential for improving the health of Pacific peoples and creating healthy Pacific communities. Pacific research encompasses various approaches to integrating cultural worldviews, beliefs, practices and concepts, including indigenous Pacific knowledge systems, conceptual frameworks and models of health such as fonofale. These Pacific frameworks and methodologies provide for the perspectives of Pacific peoples to be engaged with and represented in culturally appropriate ways. In research that targets the Pacific population, Pacific peoples should participate in all levels of decision-making about and implementation of the study.
- 7.4 These standards highlight significant issues that researchers of both Pacific and non-Pacific ethnicity should be aware of when conducting research with Pacific peoples. They also promote research that empowers both researcher and researched. They acknowledge that Pacific studies will be diverse and should be framed and shaped according to the context of the research and researched groups. Specifically, these standards focus on the consultation process as the vehicle through which these issues can be pragmatically realised and acknowledged during the research process.

Standards

- 7.5 A research protocol must demonstrate cultural integrity and should be developed only after the researchers have established meaningful relationships with the ethnic communities involved.
- 7.6 Pacific health research protocols must describe how the study will address the inequities in health outcomes of Pacific peoples.
- 7.7 Researchers should aim to understand Pacific dimensions of health as well as the basis on which Pacific engagement in research is founded.
- 7.8 Researchers should take protective measures to safeguard indigenous Pacific knowledge and knowledge holders appropriately.

Commentary

- 7.9 A strategic priority of the New Zealand Health Research Strategy 2017–2027¹¹ is to ‘invest in research that results in equitable outcomes for Pacific peoples and helps them to lead independent lives’.
- 7.10 Research shows many Pacific peoples experience financial, cultural, logistical, physical and linguistic barriers to their access to and use of services across the health and disability sector.¹² These barriers are key reasons why Pacific peoples are not benefiting from health services as much as other groups.¹³ Therefore, it is important that researchers understand the Pacific dimensions of health (such as family, spiritual, mental, physical and environmental dimensions) and how these dimensions interact. In addition, they should provide a holistic view of Pacific health, as well as the factors that influence whether Pacific peoples engage in health research, including:
- Pacific worldviews of what causes diseases
 - respect for Pacific cultural perspectives, norms and values, including Pacific peoples born in the Pacific Islands region and those born in New Zealand
 - a strong and genuine relationship, based on trust, with Pacific leaders and communities.
- 7.11 To develop a better understanding of these dimensions, researchers are encouraged to build their cultural knowledge of the Pacific communities and their values. Important Pacific values include 'aiga or family, collective responsibility, a sense of belonging to a community, alofa or reciprocity and interdependence, ava or respect in all forms and lotu or spirituality woven into customs and protocols (Ministry of Pacific Island Affairs 1998). By taking account of these values, researchers give Pacific peoples adequate opportunity and appropriate resources (including time) to become familiar with the processes, prospects, risks and benefits of the research proposal.
- 7.12 Researchers are also encouraged to involve a Pacific researcher, expert or advisory group to inform the conduct of a study where they expect the participation of Pacific peoples to be significant or consider that the study will have a significant impact on Pacific peoples.
- 7.13 Strong and enduring engagement with Pacific communities and consumers is required to ensure research responds to the health needs of Pacific peoples. For research that involves a community, researchers should consult with Pacific community leaders when designing the research. These may be leaders active in serving Pacific peoples in churches, clubs, academia, elders and young people and Pacific health experts, Pacific providers and services, and/or the community. Researchers must carefully consider who it is best to engage with so that those involved have sufficient knowledge to play a meaningful role.

¹¹ Ministry of Health. 2016. New Zealand Health Strategy April 2016
<https://www.health.govt.nz/system/files/documents/publications/new-zealand-health-strategy-futuredirection-2016-apr16.pdf>.

¹² Research shows that Pacific peoples can experience financial, cultural, logistical, physical or linguistic barriers to their access to and use of services across the health and disability sector. See Ministry of Health. 2014. 'Ala Mo'ui: pathways to Pacific health and wellbeing 2014–2018.

¹³ Tobias and Yeh. 2009 How much does health care contribute to health gain and to health inequality? Trends in amenable mortality in New Zealand 1981–2004.

- 7.14 Pacific research methodologies provide good-practice examples of how to engage with consumers and communities in a New Zealand context. For example, the talanoa¹⁴ methodology acknowledges the importance of respect and respectful spaces and relationships (Le Va) when undertaking research. When involving Pacific communities, researchers need to incorporate processes such as reciprocity. These practices will ensure safety for participants and the researchers in this relationship. Researchers need to be aware, however, that certain methodologies, such as research conducted in group settings, may expose participants from small Pacific ethnic groupings (eg, Fijians in Wellington or Rotumans in Lower Hutt) to subsequent harm. Where information is shared among participants, all need to be aware of confidentiality and privacy.
- 7.15 Pacific peoples seek a strong and trusting relationship with their health care provider as part of seeking pathways to health.¹⁵ Researchers should take account of this relationship in deciding whether to seek out members of these populations as research participants and should ensure any Pacific peoples who do participate are treated justly in the research.
- 7.16 Researchers are encouraged to create safe and enabling research environments that support culturally competent practice by:
- seeking ethnic-specific and context-specific advice on culturally competent practice
 - understanding the importance of communicating appropriately translated information to Pacific peoples.
- 7.17 Meaningful engagement is about establishing a long-term relationship and researchers may be asked to give back to the community after the research has finished. Researchers should:
- understand that effective 'face-to-face' consultation is critical to establishing meaningful relationships with and among Pacific people
 - understand how to consult
 - identify the people with whom they should consult.
- 7.18 In research with cultural integrity, researchers should consider what cultural concepts, norms, practices and language are important in the research process. They should involve Pacific peoples at an early stage in the research design, as well as in governance, management, implementation and analysis of research that involves Pacific peoples. Capacity and capability building is critical to improving Pacific health outcomes through research.

¹⁴ For further information on the Talanoa methodology please visit http://unfccc.int/focus/talanoa_dialogue/items/10265.php

¹⁵ Ministry of Health. 2014. 'Ala Mo'ui: pathways to Pacific health and wellbeing 2014–2018.

8 Categories of participants

Introduction

- 8.1 Researchers must consider the rights of all participants in research, but should take particular account of potentially vulnerable people whose individual characteristics and circumstances, in the context of the study, place them at increased risk of harm.
- 8.2 Research in vulnerable individuals and groups is necessary to answer questions that are important to the people with similar characteristics. For such research to be ethical, the vulnerable individuals or groups should not be a convenience sample; instead they must stand to benefit from the knowledge, practices or interventions that result from the research.

Vulnerable participants

Standards

- 8.3 Researchers should not exclude participants from research simply because they belong to a group traditionally considered vulnerable.
- 8.4 Researchers should include the least vulnerable participants where it is consistent with the study aims.
- 8.5 Potentially vulnerable participants should receive specifically considered protection.
- 8.6 All potential participants should have appropriate support available to help them make reasonable decisions about participating in a study.
- 8.7 Researchers should assume every individual has the capacity to make an informed choice and give informed consent, unless they have reasonable grounds for believing that the individual does not.
- 8.8 People who have diminished capacity to make decisions about their participation in a study are entitled to make informed decisions to the extent that their level of capacity allows.
- 8.9 Researchers must identify and take steps to minimise the risks of any unequal relationship that might restrict a person's freedom to consent to participate in research.
- 8.10 Researchers should only conduct research with children if comparable research with adults could not answer the same question and the purpose of the research is to gain knowledge relevant to the health needs of children.
- 8.11 Researchers must not exclude women, including pregnant women, from health-related research unless they have a legitimate scientific justification.

Commentary

Potentially vulnerable participants in research

- 8.12 Participants with specific characteristics may be vulnerable, meaning they are at increased risk of being wronged or harmed. Traditionally members of groups considered to have characteristics that may increase their risk of harm have included:
- people receiving welfare benefits or social assistance, people living in poverty and the unemployed
 - people who see participating in research as the only way that they can access medical care
 - ethnic minorities
 - homeless people, immigrants, refugees and displaced people
 - disabled people or those with impairments (eg, visual)
 - people with incurable or stigmatised conditions or diseases
 - people who are physically frail, for example because of age and co-morbidities
 - vulnerability related to gender, sexuality and age
 - individuals involved in illegal activities
 - people with substance abuse issues
 - people with mental health issues
 - people with limited time to consider whether they will participate in a study, such as in emergency care research
 - incarcerated people, such as those in prison, mental health facilities or other institutions
 - people with terminal illness
 - some older people
 - sex workers
 - people experiencing family violence
 - people experiencing physical, psychological or emotional, financial, pharmacological or spiritual abuse, or neglect.
- 8.13 However, researchers must avoid making judgements about excluding such groups based on stereotypes. A participant's individual vulnerability depends on context as well as group characteristics and can vary between circumstances. Researchers should not think solely in terms of entire groups being vulnerable. Instead, they should look for the specific characteristics and contexts that may create vulnerability, particularly where multiple risk factors co-exist, and address them with appropriate protections.
- 8.14 Researchers must balance the rights of vulnerable individuals and groups and the benefits they gain from participating in research against their increased risk of harm. Researchers must consider and include special protection of their rights and welfare.

Diminished capacity to consent

- 8.15 Capacity is the everyday ability for individuals to make decisions or to take actions about matters that affect them. Capacity may depend on the particular context as well as the nature and complexity of the decision involved. To be considered competent, participants should be able to understand the information relevant to the decision to participate in research, assess it, retain it, make a decision and communicate that decision.
- 8.16 Where researchers have reasonable grounds for believing that participants may not have the capacity to consent to the research, the research protocol must include a method for determining a person's capacity to consent. Researchers also need to take into account the level of complexity of the study in considering capacity to consent.
- 8.17 Capacity to provide informed consent can change over time so researchers must consider the need to reassess a participant's capacity during the study.
- 8.18 Participants may have diminished capacity to consent due to a number of factors; for example, early dementia or other brain disease, brain trauma, drug intoxication, pain, distress, psychiatric disease or reduced intellectual capacity. Where an individual has diminished capacity, that individual still has the right to make informed choices and give informed consent, to the extent appropriate to their level of capacity. Such a person may be able to exercise the right to consent to participate in research through supported decision-making. Supported decision-making differs from substituted decision-making or proxy consent in that the latter approaches do not suitably involve the participant in the decision-making process. The role of supporters (eg, friends, family, whānau) is to facilitate the person's decision-making process. The potential participant should choose these supporters and they should have no conflict of interest.¹⁶ The level of support should reflect the level of complexity in a particular study and be sufficient to enable someone to make a decision about whether to participate.
- 8.19 For guidance on research with an individual who has inadequate capacity to provide informed consent, even with appropriate support, see [Chapter 9](#).

Participants in a situation of power imbalance

- 8.20 Unequal power relationships may pose a risk in a study depending on who is conducting the research and in what context. Relationships that may create risk include those between doctors and patients; people in residential care or supported accommodation and their caregivers; students and teachers; prisoners and custodians; refugees and government employees; members of the military and their superiors; committed mental health patients and health professionals; employees and their employer; and service providers and other especially vulnerable communities who are receiving the service.
- 8.21 Hierarchical relationships may limit the extent to which consent to participate in research is truly voluntary when potential participants expect that they will get preferential treatment if they agree or when they fear that they will be disadvantaged if they refuse. Declining to participate in or deciding to withdraw early from research should not result in any negative consequences, such as unfair discrimination, a lower level of care or dismissal from employment.

¹⁶ United Nations. 2006. Convention on the Rights of Persons with Disabilities, Article 12.

- 8.22 Hierarchical relationships may compromise a participant's privacy outside the study. For example, research in a workplace may reveal the personal medical information of an employee-participant to the employer-researcher. Equally, it is extremely difficult to protect participant confidentiality when undertaking research in environments that intrinsically lack privacy, such as prisons, rest homes, hospitals and workplaces.
- 8.23 Researchers must also consider the potential for the power imbalance to influence study results. For example, individuals in an unequal power relationship may be unwilling to answer sensitive study questions honestly (such as questions about sexual or illegal activity). Alternatively they may over-report benefits because they want to please the researcher by providing the answers they believe the researcher wants.

Managing unequal power relationships

- 8.24 Researchers should take account of the vulnerability arising from unequal power relationships in deciding whether to seek out members of certain populations as research participants. Participants in imbalanced power relationships may be vulnerable to being over-researched where researchers have relatively easy access to them as research populations. They should neither bear an unfair share of the burden of participating in research nor be excluded from its benefits.
- 8.25 Researchers must identify and take steps to minimise the risks of any unequal relationships. Suitable steps may include informing participants of their freedom to withdraw or decline to participate, using an independent person to undertake the consent process or providing an independent advocate to participants to support their decision-making.

Research in children and young people

- 8.26 Children are not simply small adults. Research involving children and young people is important to understand their unique physiologies and health and disability needs. However, the manner in which the research is conducted should acknowledge that additional protections are necessary for the safety and emotional and psychological security of the child or young person.
- 8.27 Research involving children and young people raises particular ethical concerns about:
- their capacity to understand what the research involves and, therefore, in the case of adolescents, whether their consent is sufficient for them to participate
 - the potential for undue influence from parents, peers, researchers or others to participate in research
 - conflicting values and interests of parents and children.
- 8.28 Before undertaking research with children and/or young people, the researcher must ensure that:
- if a range of age groups can answer the study question, the study involves older children in preference to younger ones
 - people experienced in working with children design, supervise and conduct the research

- if the child is under 16 years old and lacks the necessary capacity to give legally effective consent, the researcher gets consent for the child to participate from their parent or legal guardian
- if consent is provided by a parent or guardian, the researcher still gets the child's assent to participate whenever possible and respects a child's refusal to participate in research unless:
 - the purpose of the research procedures or interventions is to provide potential therapeutic benefit to the child participant, and
 - the child would receive therapy for a condition for which there is no medically acceptable alternative
- if a child turns 16 during the course of a study, the researcher seeks their consent to continue participation.

8.29 Only one parent or legal guardian is required to give consent on the child's behalf. If the research significantly differs from standard care, the researcher should consider the views of the other parent or other legal guardians. The researcher should give the person giving consent on the child's behalf the time to consult with any other legal guardian. If the researcher becomes aware that the person who gave consent on the child's behalf has lost their authority to give such consent, they should get consent from the child's new legal guardian as soon as practicable.

Developing capacity and consent versus assent

8.30 Researchers must respect the developing capacity of children and young people to be involved in decisions about participating in research. The level of maturity of each individual child or young person affects whether their consent or assent is necessary and/or sufficient to authorise participation. It is not possible to attach fixed ages to each level, as this varies from child to child. A child or young person may also be at different levels of maturity for different studies, depending on the kind and complexity of the research. However, participants aged 16 years or older must provide their own informed consent.

8.31 Different levels of maturity and of a person's corresponding capacity to be involved in the decision include:

- infants and very young children, who are unable to take part in discussion about the research and its effects
- young children, who are able to understand some relevant information and take part in limited discussion about the research, but whose consent is not required, although researchers should get their assent
- young people of developing maturity, who are able to understand the relevant information but who remain vulnerable because of their relative immaturity. The assent of these young people is required, but is not sufficient to authorise research
- young people who are mature enough to understand and consent, and are not vulnerable through immaturity in ways that warrant the need for additional consent from a parent or guardian.

- 8.32 Research protocols must include a method for establishing to what degree child participants are able to provide informed consent. To have adequate competence, the child must have sufficient understanding and maturity to fully comprehend the proposed treatment or research participation. Consent and assent are dynamic, continuous processes; researchers should check them throughout the study to ensure they are maintained. If during the study the child reaches the capacity to give legally effective consent, the researcher must get the child's consent, which will replace their parents' consent on their behalf.
- 8.33 Researchers must provide a range of suitable information sheets, consent forms and assent forms to a level appropriate to the literacy levels of all participants. Information sheets for children should be child friendly and provide a suitable level of information, taking the study's level of risk and the nature of the children's involvement into consideration. Illustrations may be helpful. Researchers should engage even young children with very limited cognitive capacity, discussing the research and its likely outcomes at their level.
- 8.34 Researchers should keep research data on the child participants for 10 years after the child has reached the age of 16 years. Children have the right to withdraw consent to the continued use or retention of personally identifiable health research data (and tissue) once they reach the age of 16 years.
- 8.35 Families and children must not receive financial or other material incentives that may unduly influence the decision to participate in the research. Children may be offered a suitable koha or gift after the study to acknowledge their participation. This process is aligned to the concept of reciprocity.
- 8.36 Researchers need to protect children if study participation involves the disclosure of sensitive information, such as sexual activity, drug use, or abuse. Special provisions for protecting the children's privacy may also be necessary to ensure children provide accurate information, so they do not feel a need to lie to please their parents. For example, if a study with children involves pregnancy testing, researchers should not restrict this testing to children who disclose that they are sexually active. Targeted testing may risk missing participants who fail to disclose sexual activity or may inadvertently expose the child to risk.¹⁷

Research in women

- 8.37 Women have historically been excluded from much health-related research because of their childbearing potential. However, as women have distinctive physiologies and health needs, they must be included in research wherever possible. Researchers should not exclude women from research without sufficient justification simply because they are biologically capable of becoming pregnant. For results to be generalisable, researchers must recruit a sufficient number of women so that they reliably account for gender differences in treatment, disease processes or basic biological processes.

¹⁷ For more information regarding ethical research involving Children please visit www.childethics.com.

- 8.38 Specific circumstances in which women could be vulnerable in research include: studies with sex workers; research on family violence; studies with trafficked women; studies of abortion; and research with women from a cultural context where it is customary for them to make decisions in conjunction with a spouse or male relative. When women in such situations are potential participants in research, the researcher must ensure that the woman participating is freely giving her informed consent and provide suitable circumstances for getting this consent.

Pregnancy

- 8.39 As pregnant and breastfeeding women have distinctive physiologies and health needs, research designed to build knowledge relevant to the health needs of the pregnant and breastfeeding woman is important. Researchers must only begin research on pregnant women after carefully considering the available data and identifying important gaps within it. While researchers must not consider pregnant women to be vulnerable in any research simply because they are pregnant, specific circumstances may require special protections. Researchers should carefully consider whether the study may pose risk to the fetus, including stress or pain in-utero. The wellbeing and care of the woman who is pregnant or breastfeeding and of her fetus or baby always take precedence over research considerations.
- 8.40 Many study protocols remove women from participation when they become pregnant during the research. However, researchers should not automatically remove these women from the study. Instead, they must carefully consider whether it is appropriate for them to continue to participate.

9 Informed consent

Introduction

- 9.1 Informed consent is a dynamic process that begins with the researcher's first contact with a potential participant and continues through to the end of the participant's involvement in the research. The informed consent process requires effective and reciprocal communication between the researcher and potential participants.
- 9.2 Researchers have a duty to provide potential participants with the information and the opportunity to give their free and informed consent (usually in writing) to participate in research, or to decline to do so.
- 9.3 In the context of research in New Zealand, *mana tangata* (autonomous individual) refers to someone who chooses to participate in research and their right to be appropriately informed of risks of harm to their individual or collective *mana*. Researchers must consider identifying risks of harm (individual and/or collective) and whether those risks of harm are fairly distributed. Through clearly explaining the requirements for informed consent and recognising the place of verbal consent in some Māori settings, researchers must demonstrate respect for the *mana* of Māori participants.
- 9.4 Informed consent contributes to a number of ethically important concepts, such as transparency, supporting individual autonomy, protecting participants' welfare, promoting agreement with participants' values, promoting trust, satisfying regulatory requirements and promoting integrity in research.
- 9.5 Obtaining the informed and voluntary consent of participants is the default starting point in these standards. In limited circumstances, aspects of the consent process may be [modified](#) or the requirement to obtain consent may be [waived](#).

Standards

- 9.6 Participants' consent to participate in research must be voluntary.
- 9.7 Before making their decision to participate in research, participants must receive all information relevant to their decision to participate and researchers must communicate that information effectively in plain language that potential participants can understand.
- 9.8 Information given to potential participants must cover the aims, methods, sources of funding, possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of harm of the study and the discomfort it may entail, post-trial access and any other relevant aspects of the study. [View participant information sheet requirements](#).
- 9.9 Any modification to informed consent requires approval from an ethics committee.
- 9.10 Researchers must seek and obtain the consent of individual participants before those participants begin to be involved in the research, except in the circumstances outlined in the section on [research without consent](#).
- 9.11 The study protocol must detail the process for obtaining consent.

- 9.12 Researchers should give potential participants sufficient time and support to consider whether to participate in the study, as appropriate to the context of the study.
- 9.13 The person obtaining informed consent must be knowledgeable about the research and capable of answering any questions from potential participants.
- 9.14 Participants should be offered the opportunity to ask questions and receive answers before or during the research. Researchers should make every effort to address those questions in a timely and comprehensive manner.

Commentary

Suitable processes for obtaining consent

- 9.15 Meeting the needs of potential participants may require different approaches. For example, researchers may need to put in place a [supported consent](#) process or provide culturally appropriate information for potential participants. Researchers must consider the environment and timeliness of the consent process.
- 9.16 Consent must occur before study processes begin, including personal data collection and diagnostic testing necessary for eligibility screening.
- 9.17 Researchers should consider the circumstances of the potential participant during the consent discussions. They must recognise that it is important for participants to have support when in a stressful situation.
- 9.18 Researchers should also document participants' consent. Where participants give consent in a form that is not written, researchers must record the evidence of consent in some other manner (eg, audio, video, electronic, written note in file). Consent can also be demonstrated by a participant's actions, such as returning a completed questionnaire.
- 9.19 If participants face barriers, including language barriers, it may be necessary to get help from an intermediary, such as an interpreter or advocate. Involving intermediaries may raise confidentiality issues.
- 9.20 If a participant is unable to read, an impartial witness should be present during the entire informed consent discussion. By signing the consent form, the witness attests that the information in the participant information sheet and consent form and any other written information was accurately explained to the participant verbally, that the participant apparently understood that information, and that the participant freely gave informed consent.
- 9.21 Researchers must notify participants of any substantial changes during the study that may affect them. Where they significantly amend the study so that it substantially changes from what participants originally agreed to, researchers must seek participants' consent to continue to take part.
- 9.22 For studies conducted over a longer period, researchers should establish an ongoing dialogue about the research and give participants the opportunity to ask questions throughout the study. If they do not significantly amend the study, researchers should consider participants' consent to be ongoing unless they have reason to believe a participant is withdrawing consent.

- 9.23 If a study requires several interactions between the participant and the researcher over time, or if the participant may be considered ‘vulnerable’ for any reason, the researcher should verbally check that consent is ongoing.
- 9.24 Participants have the right to withdraw at any point in the study without retribution.
- 9.25 Researchers must give potential participants adequate time and opportunity to absorb the information provided, ask any questions, and discuss and consider whether they will participate. How much time is needed for this first phase of the consent process will depend on such factors as the magnitude and probability of harms, the complexity of the information provided and the setting where the information is given.
- 9.26 Participants may be faced with making multiple simultaneous consent decisions about clinical care, research participation and future unspecified use of tissue. In such circumstances, researchers should take into account the [recruitment](#) context and consider ways to reduce risk of undermining the informed consent process. For example it may be appropriate to undertake the consent processes for each aspect at a different times, as well as being identifying [conflicts of interest](#) and avoiding [therapeutic misconceptions](#).

Consent must be voluntary

- 9.27 Voluntary consent is an ongoing and important expression of a participant’s free will. The consent process must protect participants from coercion, deception, manipulation or other undue influence. Researchers are responsible for ensuring that participants know that they are free to accept or decline an offer to participate in a study, and that they will not experience any disadvantage by making either decision.
- 9.28 Information in Chapter 13 on [conflict of interest](#) and in Chapter 8 on [categories of participants](#) covers participants who may be more likely to experience influence on the voluntary nature of their decision to participate.

Consent must be informed

- 9.29 Effective communication is an essential feature of informed consent. Researchers must provide participants with all information relevant to their initial and ongoing consent to participate in the research. Participants have a right to the information that a reasonable person, in that person’s circumstances, would expect to receive.
- 9.30 Researchers must provide information in a form, language and manner that participants can understand. Information provided to participants, and discussion of this, should be appropriate to the individual, taking into account their health literacy and their cultural and language background.
- 9.31 Informed consent involves balancing participants’ right to be fully informed against not overburdening participants with information that reduces their ability to provide effective informed consent. Participant information sheets should not contain excessive information. Their main purpose should be to inform participants, rather than to protect researchers or sponsors or to achieve any other purpose.
- 9.32 The information provided to participants should be proportional to the risk associated with study participation and suitable for participants’ circumstances. As a general rule, the higher the risks participants face through their participation in a study, the more detailed the information and the greater the support they receive need to be.

- 9.33 In some research, individuals may overestimate the likelihood or degree of benefit of the experimental intervention ('therapeutic mis-estimation'), overlook the implications of study participation or mistake research procedures for therapeutic ones ('therapeutic mis-conception'). Researchers should make particular efforts to obtain a valid informed consent by ensuring that participants understand the implications of participation.
- 9.34 Researchers must provide participants with the following information, which will usually be in the form of a participant information sheet, as relevant:
- an explanation of the nature of the study, which covers:
 - the purpose of the research, including its expected contribution to knowledge
 - the features of research design, including an explanation of randomisation, blinding or [placebos](#)
 - the nature and sources of funding and resourcing of the study, and the institutional affiliations of the researcher(s)
 - any actual or potential conflicts of interest or commitment and how they will be managed
 - details of ethics approval, including the reference number
 - why the individual may be suitable for the study
 - what participation in the study will mean for participants, including:
 - what will be done in the study
 - how participation will differ from not being part of the study
 - the time involved in participation
 - any inconveniences resulting from study participation, such as time off work
 - the nature, purpose and expected number of any extra tests to be performed during the study
 - a discussion of any risks, including foreseeable side effects, pain and discomforts, which:
 - describes the nature of risks for particular types of participants (eg, women of childbearing age)
 - expresses the likelihood of risk of harm as an event frequency (eg, one in ten)
 - defines the severity of potential harm in terms of the damage that it would cause (eg, discomfort, pain, trauma)
 - communicates any [risks of harm](#) that may exist for a participant's family, whānau, hapū or iwi
 - possible benefits of research participation for individual participants, communities, hapū or iwi; and society at large; or any contributions to scientific knowledge
 - what and how any [findings](#) that are relevant to the health of participants will be communicated to participants
 - the extent of the researchers' responsibility to provide care for participants' health needs during and after the research, who will pay for any costs associated with such care and the relationship between the participant's usual health care provider and the research team

- an explanation of participants' rights, which covers:
 - the voluntary nature of participation, including that participants are free to withdraw from the study at any stage (to the extent possible)
 - the right of participants to access tissue and/or data about themselves collected as part of the study
 - how participants will be told of any new information about adverse or beneficial effects related to the study if it becomes available during the study and may have an impact on their health
 - what arrangements will be made for the privacy and confidentiality of individuals, including the confidentiality of data in which individuals are identified or potentially identifiable
 - any limits, legal or otherwise, to the researchers' ability to safeguard confidentiality and the possible consequences to participants of a breach in confidentiality
 - arrangements for personal [compensation](#) for injury
 - what costs will be reimbursed and how participation will be recognised
- information about what will happen after the study, which covers:
 - whether an intervention or care related to the research will be available to participants after the study and, if so, under what conditions (including any cost to them)
 - how the researchers will communicate the research findings to participants and communities and the expected timeframe for this
 - how the researchers will disseminate research results and whether participants will be identified directly or indirectly
 - if and how the research findings will be translated into health care
- whether the research findings may be commercialised and any ownership rights participants may have over these
- whether researchers may remove participants from the study for any reason
- suitable contact details, including those for:
 - the researchers
 - a suitable cultural support person
 - an independent advocacy service (eg, the Health and Disability Commissioner)
 - the ethics committee that has approved the study
- information about how study data will be used and where it will be stored (including any [specified or unspecified future](#) use or uses)
- whether any [data linkage](#) will be performed and whether the data will be stored in a [databank](#)
- the form in which the data will be accessed, used and stored during the life cycle of the research data (identifiable, re-identifiable, non-identifiable)
- how long the data will be retained
- who will access the data and the form in which it will be accessed and shared
- whether data will be transferred to other countries and, if so, the impact (if any) on participants' rights
- whether participants may be able to withdraw their data, including up to what point they can withdraw it

- procedures for withdrawing data
- procedures for destroying data
- information about the use of their **tissue**, which covers:
 - how their tissue will be stored, used and disposed of, including any processes that will be followed to respect their personal or cultural sensitivity
 - the extent to which their tissue will be reasonably identifiable, and how their privacy and confidentiality will be protected
 - whether or not research using their tissue is likely to provide information that may be important to their health or to the health of their blood relatives or their community, how this kind of information would be managed and whether they have a choice about receiving the information
 - whether their tissue and associated data may be distributed to other researchers, including those outside New Zealand
 - their right to withdraw consent for the use of their tissue and associated data in research, and any limitations that may be relevant to their withdrawal of consent; for example, as a consequence of the removal of identifiers or the prior distribution and/or use of their tissue
 - any relevant **financial or personal interests** that those engaged in collecting, processing, storing, distributing and using their tissue may have
 - any potential for commercial application of any outcomes of the research involving their tissue, how this will be managed and who, if anyone, will benefit from them
 - whether they may be able to have leftover tissue samples returned to them and whether the tissue can be disposed of, including that any wishes about the method of disposal will be recorded at the start of the research and taken into account at the time of disposal.

Electronic consent

9.35 Electronic procedures for consent, either online or in other digital formats, are increasingly replacing printed copies of participant information sheets and consent forms. The electronic consent must contain all elements of informed consent in a language the participant can understand. Interactive formats, if used, should be simple to navigate. Researchers should not use electronic methods if participants, for any reason, indicate a lack of comfort with electronic media.

Duration of consent – specified and unspecified use of data and tissue

9.36 Information and tissue collected about or from research participants is for use in the specific project to which they have consented. If at the time of consent it is possible to identify future studies that are either an extension of the current study or in a closely related area, researchers should inform participants of these later studies and invite them to give an extended consent for data use. Where it is not possible to specify the nature of the research for which future researchers would like to use that data or tissue, current researchers may ask for unspecified consent for future use. All such future research projects must undergo appropriate ethical review.

Consent for future unspecified use of tissue

- 9.37 New Zealand individuals are able to give consent to their tissue being used for future unspecified research, provided that they have received sufficient information and options for consent through a distinct consent¹⁸ (Ministry of Health 2007). What makes this storage ethically justifiable is a combination of informed consent, transparency and good governance structures. All tissue stored beyond the duration of a research study is considered biobanking. See [Biobanks](#) for more information.
- 9.38 When donors give consent for future unspecified research, researchers must:
- indicate the type and nature of the research to be carried out and its implications for the donor, where possible
 - explain why the potential donor is being approached for their tissue and specifically what tissue is being sought
 - state where and for how long a tissue sample will be stored, how it will be disposed of and whether there is a cultural protocol for its disposal
 - identify known possible researchers or institutions that might use the tissue sample, if possible
 - state whether the donor's sample is likely to be sent overseas and, where possible, to what country or countries
 - acknowledge that all future unspecified research in New Zealand will be subject to ethical review. However, when a tissue sample is sent overseas, unless it is sent in conjunction with a New Zealand study, future research is likely to be considered by an overseas ethics committee without New Zealand representation
 - state whether the donor's identity and details will remain linked with the sample or whether the sample will be delinked
 - state whether the donor can withdraw consent for the use of human tissue samples in the future
 - state that, if a donor consents to a tissue sample being unidentified or delinked, they relinquish their right to withdraw consent in the future
 - state whether the donor may be contacted in the future about their tissue sample
 - state whether, and under what circumstances, information about the future unspecified research will be made available to the donor and/or (where relevant) their clinician
 - acknowledge that the donor will not own any intellectual property that may arise from any future research
 - acknowledge that the donor's decision about the consent for use of their tissue sample for unspecified future research will in no way affect the quality of a donor's current or future clinical care.

¹⁸ Ministry of Health. 2017. Guideline for the use of human tissue for future unspecified research purposes.

Consent requirements for databanks – extended or broad consent

9.39 Researchers must give participants adequate information about the inclusion of their data in [databanks](#), who may use it and how it may be used. When seeking consent for unspecified use, researchers must clearly explain the terms of consent and the wide-ranging implications of such data use. In particular, they must advise participants of:

- the purpose of the databank
- the nature of the data to be collected (identifiable, re-identifiable or non-identifiable)
- rights of withdrawal of consent and, in particular, the possibility that where data is made non-identifiable, the individual may not be able to know what is done with their data and will not have the option of withdrawing their consent
- the future foreseeable uses of the data, whether limited to an already fully defined study or extending to a number of wholly or partially undefined studies and the intended goal of such use (whether only for basic or applied research or also for commercial purposes)
- the procedures for return of results, including incidental findings
- the rules of access and who will manage that access
- how confidentiality and privacy is protected
- where applicable, commercial use and benefit sharing, intellectual property issues and the transfer of data to other institutions or third countries
- the conditions and duration of storage
- the ways in which the individual can contact the databank or registry custodian and remain informed about future uses
- the ways in which the individual can request corrections of mistakes or omissions and, in particular, the possibility that, where data is made non-identifiable, the individual may not have the option of correction
- the risks and burdens associated with collection, storage and use of data.

9.40 The ethical acceptability of extended and broad informed consent relies on proper [governance](#).

Modifying the consent process

9.41 Sometimes, because of a study's design or the characteristics of the research population being studied, it is necessary to modify the informed consent process. Alterations to the traditional consent model have ethical implications, which researchers have a duty to evaluate when proposing modifications to consent. To perform such an evaluation, researchers must explain how traditional consent would impact on the study, and examine to what degree proposed alternatives affect participants' rights.

Withholding information and deception

- 9.42 Where deception and/or concealment are part of the research design, the researcher must justify this choice to an ethics committee, according to the following criteria.
- No suitable alternative methods are available.
 - Participants are not exposed to increased risk of harm due to the deception or concealment.
 - The study protocol defines the extent of deception or concealment.
 - Researchers disclose the deception or concealment adequately and promptly to participants, and debrief them, as soon as it is appropriate and practicable.
 - Researchers offer participants the option of withdrawing study data that they collected through deception or concealment.
 - The deception or concealment will not compromise the relationship between the community and the researchers or research.
- 9.43 In limited circumstances, providing very specific information about the study in advance of seeking consent could prejudice the purposes of collecting data, which would compromise the **scientific validity** of the study (eg, advising participants about which arm of a trial they will be allocated to). In such cases, researchers should ask potential participants to **consent** to remain uninformed about some procedures until the research is completed. After their participation in the study ends, the researchers must then give participants the information they withheld at the start.
- 9.44 In other cases, because a request for permission to withhold some information could jeopardise the validity of the research (eg, when participants may modify their behaviour in response), the researchers cannot tell participants that they have withheld some information until the data has been collected. For such research, before analysing study results, researchers must give participants the information that they withheld earlier and give them the option of withdrawing their data collected during the study. Before the study starts, researchers must also consider how participants' withdrawal of their data could impact on the validity of the study.
- 9.45 Researchers may sometimes deliberately misinform participants in order to study their attitudes and behaviour. Active deception of participants is considerably more controversial than withholding information. Researchers must be aware that deceiving participants may wrong as well as **harm** them; participants may resent not having been informed when they learn that they have participated in a study under false pretences.
- 9.46 If actively deceiving participants is necessary to maintain the scientific validity of the research, researchers must justify the deception and obtain the approval of an ethics committee for it. After the research is completed, researchers must inform participants of the deception and the reasons for it, in a process often called 'debriefing'. Debriefing is an essential part of trying to rectify the wrong of deception. Where participants disapprove of having been deceived for research purposes, researchers must offer them an opportunity to withdraw their data collected through deception.

Integrated consent

- 9.47 Learning health care systems hold promise for improving medical care by integrating the delivery of medical services with clinical research. Seamlessly embedding research into routine clinical care can be difficult when the traditional lengthy process of informed consent for research participation is required. The standard consent process for research may take time from ordinary clinical care and compromise the generalisability of research by failing to mirror the experience of patients in the real-world clinical setting.
- 9.48 In very limited circumstances, researchers may be able to justify using an integrated consent protocol, in which consent to participate in research occurs as part of a clinical discussion. This would occur where the research is comparing two or more clinical options that are available as part of standard care, for example in [comparative effectiveness research](#). With integrated consent, the usual clinical discussion about treatment includes explaining that participants will be randomly assigned to one of the clinical options, but also informs them that their health data will be collected and used for the purposes of research. Consent to treatment must be sought prior to consent for research.
- 9.49 However pragmatic such trials may be and even in low-risk comparisons of standard of care, significant practical and ethical tensions with integrated consent remain, particularly with respect to patient rights and individual autonomy. Therefore, and unless they manage these concerns appropriately, researchers should not proceed with research protocols involving integrated consent procedures justified in terms of expediency or convenience. By integrating consent into the clinical discussion, they are likely to give information to participants that is substantially briefer for practical reasons than a written participant information sheet usually provides; notably, explicit statements about voluntariness and confidentiality tend to be less detailed. The discussion must clarify that the patient will still receive treatment if they choose not to participate in the research and it must distinguish between consent to treatment and consent to participate in research.
- 9.50 At a minimum, integrating consent for research into the interaction between health professional and patients/participants must include the basic aspects of voluntary and informed consent. In particular, researchers must:
- make the research component transparent, including randomisation, the use of data and any additional research procedures, and distinguish it from treatment
 - explain the risks, benefits and rationale of the research component, where the risks of the research must be no more than minimal
 - if they do not get separate written consent, document the consent processes and the discussion with the patient
 - respect the preferences and values of the potential participants.
- 9.51 Researchers must present ethics committees with compelling arguments and demonstrate why a pragmatic trial would be impracticable with traditional informed consent. It is imperative that the researcher obtaining informed consent is experienced in obtaining consent and is able to clearly separate clinical and research components for participants. They must also weigh these reasons of practicality against the impact on patients' rights, including the implications of reducing transparency and limiting patients' freedom of choice about treatment options.

Abbreviated consent in medical emergencies

- 9.52 In some circumstances, researchers may be able to justify using an abbreviated consent process to enrol participants if following a standard consent process could seriously compromise that individual's health. For example, certain types of medical emergency practice can be evaluated only when a particular medical emergency occurs that necessitates the practice.
- 9.53 An abbreviated consent process may be appropriate if the potential participant faces a serious threat that requires immediate intervention and the risk from the research is no greater than that involved in standard care. Alternatively the research intervention may be clearly justified if the participant is likely to directly benefit from it.
- 9.54 Subject to all applicable legal and regulatory requirements, researchers must only conduct research involving medical emergencies if it addresses the emergency needs of the individuals involved and meets the criteria established in advance of such research.
- 9.55 With abbreviated consent, researchers must still give potential participants the information a person in their position would expect to be told, although this may be briefer than the information they would provide in the standard consent process. Participants must still consent to participating in the study before they are enrolled.
- 9.56 When a participant's circumstance becomes more stable, researchers should offer them full information about the study. They should also reaffirm the participant's fully informed consent to continue to participate in the study and to allow their already collected data to be included in the study.
- 9.57 If the participant is unconscious or lacks capacity to understand the risks, methods and purposes of the study, see the section on research with [participants unable to provide informed consent](#).

Research without seeking consent

- 9.58 This section relates to studies where researchers are not seeking consent from participants.
- 9.59 New Zealand law has mechanisms where, under certain conditions, it is permissible to waive consent for use of health information¹⁹ and human tissue²⁰ collected for another purpose, for research purposes. New Zealand also has legal mechanisms to provide health services, which may include research, to individuals without their consent.²¹
- 9.60 New Zealand has no legal mechanisms for a 'general' waiver of consent, as is available in other countries. Research methods such as [cluster controlled trials](#) or community intervention studies often seek a waiver approach because the interventions involved are being implemented at a system, group or community level rather than an individual level. Although in some cases it may be ethically justifiable to waive consent for these studies, such a waiver is not possible in New Zealand. These studies must have individual informed consent in order to meet New Zealand legal requirements.

¹⁹ Privacy Commissioner. 2008. Health Information Privacy Code 1994.

²⁰ Human Tissue Act 2008.

²¹ Health and Disability Commissioner. 1996. Code of Health and Disability Services Consumers' Rights.

9.61 Other research designs may involve repurposing existing tissue or data for a research project without obtaining individual consent. The default position is that the use of health information or tissue requires consent at the individual level. However, a waiver is legally available for use of health information and human tissue in New Zealand; researchers must clearly justify why they need to apply that waiver, outline it in the study protocol and gain approval for it from an ethics committee.

Opt-out consent

9.62 With 'opt-out consent' (sometimes called 'passive consent'), potential participants inform the researcher only when they do not wish to participate. Researchers must take care that this recruitment method does not cause harm by individuals becoming unwitting participants.

9.63 This method of consent reflects a balance between entirely waiving consent for use of data and requiring prospective consent, and is commonly used with registries. Researchers must only use an opt-out approach in studies that could also meet a waiver of consent for use of health information, because the opt-out or passive consent does not meet the legal requirements of prospective informed consent.

9.64 An opt-out approach to recruitment may be appropriate when opt-in consent is neither practical nor feasible. If an opt-out procedure is to be ethically acceptable, the researcher must be able to justify it by ensuring that:

- potential participants have received appropriate materials informing them about the recruitment and study
- participants are made aware of the existence of the opt-out procedure and are informed that they can choose not to participate or not to have their personal information included in the study
- participants are offered clear and accessible ways to decline to participate and a reasonable time period in which to do so
- potential participants are given an opportunity to speak with the researchers if they are confused by the instructions or need to discuss the study further
- privacy concerns for sensitive research are addressed
- being involved in the research carries no more than minimal risk to participants
- the public interest in the research outweighs the public interest in protecting privacy
- the requirement for opt-in consent would compromise the necessary level of participation to achieve study aims
- data [management and governance](#) are in line with appropriate standards
- the opt-out approach is not prohibited by law.

Secondary use of existing data or tissue samples

9.65 Gaining informed consent to use identifiable data or tissue in research should always be the default starting point. Where researchers propose to use identifiable data or tissue without specific consent for research (eg, where data or tissue was collected for clinical investigation, or the proposed data or tissue use is not consistent with the scope of the original research consent), researchers must satisfy an ethics committee that all of the following conditions for a waiver of consent are satisfied.

- There are scientific, practical or ethical reasons why consent cannot be obtained.
- The nature, degree and likelihood of possible benefits outweigh the nature, degree and likelihood of [possible harms](#), including to any participant, other individuals, whānau, hapū, iwi, Māori communities and any other groups or communities.
- Appropriate data and tissue [governance](#) plans are in place.
- There is no known or likely reason to expect that the participant(s) would not have consented if they had been asked.
- The researchers have undertaken appropriate consultation with cultural or other relevant groups, and those consulted support the proposed use.

Non-consensual research with adults who cannot provide informed consent

- 9.66 This section addresses the ethical issues concerning non-consensual research involving adult participants who cannot provide or lack the capacity to give their own consent. See the section on [vulnerable participants](#) in Chapter 8 for information on seeking consent where adults have [variable degrees of competency](#) but are considered able to provide their own informed consent.
- 9.67 Informed consent has traditionally been seen as the main way of protecting patient autonomy in research. In some studies, informed consent is not an option because the people involved in the study cannot provide consent. However, given medical treatment extends to those with impaired decision-making capacity, it is important not to exclude people from research just because they cannot consent to participate. Where populations have been excluded from research because they are unable to give consent, such as people in intensive care units, the severely disabled and those in emergency care, care or treatment options may be less strongly evidence-based because insufficient research about them is available.
- 9.68 Despite the ethical imperative for evidence-based health care, New Zealand has a strong focus on informed consent and has made this aspect of patient rights an integral part of both care and research in the health and disability sector. However, adults who cannot provide their own informed consent should not inappropriately be excluded from health and disability research so that researchers can generate evidence that is relevant to their specific health needs and unique physiologies.
- 9.69 The law must be followed at all times when carrying out research in New Zealand. NEAC's view is that the current legal situation is restrictive, potentially prohibiting some participants from accessing health research. NEAC support a two-step approach that it believes meets ethical standards in this research context but is not currently able to be conducted within the law. The approach requires the level of risk of the research to determine the acceptable benefits that enable ethical recruitment of participants who cannot provide their own consent. This is not legal and cannot be used at this time.
- 9.70 When considering the ethical justification for research that involves adults who cannot provide their own consent, researchers must balance ethical principles in each individual study, as well as in each individual case of enrolment.

9.71 This section helps to navigate these ethical tensions. It provides limits on what kind of research is ethical when participants cannot consent to it, along with safeguards that reduce the risks involved in this research context. The risks of each study will be specific to its context. Different groups of people who cannot consent will also have distinctive needs that researchers must meet. Potential participants may be capable of verbally or physically assenting, or declining, to participate in research, even if the way they express it does not meet all of the requirements for consent.

Standards

- 9.72 All options for conducting research in consenting populations must be exhausted before conducting health research with non-consenting participants.
- 9.73 Health research with non-consenting participants must be connected or responsive to the health needs or priorities of the group that the participants represent.
- 9.74 The condition that prevents participants from giving informed consent must be a necessary characteristic of the research group.
- 9.75 Researchers must conduct all such research within the law and are ultimately responsible for ensuring that their study meets all relevant requirements of legislation and guidelines.
- 9.76 Once researchers have demonstrated that the participation of individuals who are unable to consent are necessary to answer the research question, Researchers must balance risks of [harm with benefits](#). New Zealand law requires participation in all cases of health research without consent to be in the individual participants' best interest.
- 9.77 Researchers are responsible for demonstrating to an ethics committee how their research meets the ethical standards, including by [detailing the risks to individuals and the benefits to individuals and to others](#).
- 9.78 Before enrolling a non-consenting participant in a study, the researcher must take reasonable steps to identify, ascertain and consider the views of one or more other suitable people who are interested in the welfare of the participant.
- 9.79 The researcher must take reasonable steps to identify any previous situations in which a potential participant has consented or refused to participate in research (whether general or specific) and respect any such decision.
- 9.80 In some cases, it may be appropriate for researchers to seek an independent view on whether a particular participant's enrolment in a study is ethical. In the medical context, this may involve getting an independent clinical assessment.
- 9.81 If participants become capable of giving informed consent during the research, researchers must get their consent to continue to participate. This must include the option for participants to withdraw data already collected, if this is possible.

Commentary

Legal requirements

- 9.82 Whether a particular study that involves undertaking research on adults who cannot provide informed consent is legal depends on the study and on several pieces of legislation, together with common law. Relevant legislation includes but is not limited to the:
- [Code of Health and Disability Services Consumers' Rights](#), Rights 4(4), 6(1)(d), 7(1), 7(2), 7(4), 7(5) and 7(6)
 - [Accident Compensation Act 2001](#), section 32
 - [Crimes Act 1961](#), sections 61 and 61A
 - [New Zealand Bill of Rights Act 1990](#), sections 10 and 11
 - [Protection of Personal and Property Rights Act 1988](#)
 - [Mental Health \(Compulsory Assessment and Treatment\) Act 1992](#).
 - [United Nations Convention on the Rights of Persons with Disabilities](#), 2006, article 12.
- 9.83 Due to the complex legal environment it is recommended that researchers seek legal advice to ensure the research is conducted in line with New Zealand law.

Proxy consent

- 9.84 Due to New Zealand law, the group of people who can give consent for another adult to participate in health research that involves medical experimentation is smaller than is often assumed and their powers are very limited. Researchers should check the [relevant legislation](#) to ensure their enrolment process meet legal requirements.

Additional protections

- 9.85 Because adults who cannot provide their own consent cannot, at the time, protect their own interests or indicate their preferences, they also require special protections.
- 9.86 Researchers should respect the views held by the person(s) interested in the participant's welfare on whether participation would be acceptable. They should also seek this person's advice about the individual's continued involvement in the research, particularly if the study is amended. If such a person is not able to be identified and the intervention must be conducted in acute circumstances, the research may proceed without having that information available, but efforts should be made to identify the person to establish whether the individual can continue to participate.
- 9.87 When a study enrolls a participant without consent, researchers must pay special attention and make extra efforts to minimise pain, anxiety and related social harms in relation to enrolment without consent. This requirement applies especially in cases where participants may not be able to adequately communicate pain or discomfort due to their condition.

A note on ethics and the law

- 9.88 NEAC's role is to determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services. NEAC must also ensure that any advice and guidelines comply with the laws of New Zealand.
- 9.89 This requirement created a tension between providing ethical guidance that may be in conflict with New Zealand law. NEAC notes that the law on research with participants who are unable to consent restricts when research can be carried out in this population to cases where participation is in the individual's best interest. NEAC note that in some cases it may be ethically justifiable to use different calculations of benefit and harm depending on the level of risk to which the participant is exposed, as well as whether the participants in the study have potential prospective benefit derived from their involvement. This is not legal in New Zealand.
- 9.90 NEAC support a two-step approach that it believes meets ethical standards in this research context but is not currently able to be conducted within the law. The approach requires the level of risk of the research to determine the acceptable benefits that enable ethical recruitment of participants who cannot provide their own consent:
- Where the research imposes only minimal risk, the research should have the prospect of providing benefits to the participants or the group to which they belong.
 - Where the research exposes participants to more than minimal risk, there must be the prospect of direct benefit for the participant. Direct benefits should be commensurate with the level of foreseeable risk. In balancing benefit to risk, the risk / benefit ratio should be 'at least as favourable to the participants' as alternative approaches.

10 Research benefits and harms

Introduction

- 10.1 Research can generate benefits for individuals now and in the future. However, all research carries some risks of harm. Risks of harm to research participants are ethically acceptable only if they are outweighed by the potential benefits of the research. Framing and conceptualising research therefore involves not only identifying a gap in knowledge, but also thinking about who will benefit from the research, what risks of harm the research may create and who will be exposed to those risks. Striking the right balance between potential benefits and risks of harm requires attention to the context of the study.
- 10.2 To justify any risks of harm to study participants, the research must have social and scientific value. Researchers must minimise such risks and ensure that any remaining research risks are outweighed by the potential benefits to individuals, or are appropriate to the potential benefits to society and science.
- 10.3 For research in the New Zealand context, researchers should especially consider the risks taken and expected return of benefit for Māori. See [Benefits for Maori](#).

Standards

- 10.4 Researchers must identify and assess potential risks of harm. They must ensure that those risks are either outweighed by the prospect of potential benefit to the individual or appropriate in relation to the social and scientific value of the knowledge gained.
- 10.5 Researchers must minimise risks of harm.
- 10.6 After minimising all risks of harm, researchers must manage any residual risks.

Commentary

Identifying and assessing potential benefits and risks of harm

- 10.7 The ethical justification for exposing participants to risks of harm is that the research has social and scientific value. That is, it has the potential to generate knowledge and methods that can protect and promote the health and independence of individuals, the population and groups within that population.
- 10.8 In assessing potential benefits and risks of harm, researchers must:
- identify the potential benefits and risks of harm
 - assess the likelihood of potential benefits and harms occurring and their magnitude or severity
 - identify who may receive the potential benefits and who may bear the risks.

- 10.9 Benefits are events or experiences that advance the interests of one or more individuals. The categories of prospective benefits include:
- direct benefit for the individual, such as improvement in health condition
 - indirect benefit, such as feeling helpful, gaining access to medical care that may not be available outside of the study or training researchers
 - benefits to others, through generating knowledge that may improve the lives of people in the future rather than the lives of the individuals in the study.
- 10.10 Researchers must consider the potential benefits as part of their consideration of the value of the research. Although no list of benefits is exhaustive, Table 1 identifies some potential research benefits.

Table 1: Summary of some potential benefits for different parties involved in research

Recipients of benefits	Potential benefits
Participants	<ul style="list-style-type: none"> • Access to interventions or procedures • Opportunities to share experiences • Koha • Acknowledgement in publications • Feelings of doing good and making a contribution • Copies of reports
Communities	<ul style="list-style-type: none"> • Research capacity – research skills, understanding research processes • Access to interventions • Collection and protection of existing intellectual property • Gaining knowledge • Copies of reports • Sharing in new intellectual property
Māori	<ul style="list-style-type: none"> • Community development (eg, health-promoting events) • Researcher development (eg, qualifications and research experience) • Knowledge advancement (eg, research outputs; hui – meetings and seminars; and wānanga – workshops and teaching sessions) • Development of mātauranga Māori
Society	<ul style="list-style-type: none"> • Knowledge advancement (eg, research outputs, hui and wānanga) • Inclusiveness and diversity within the research system
Researchers	<ul style="list-style-type: none"> • Status and reputation • Qualifications (Masters and PhD theses) • Personal advancement, particularly enhanced publication records • Increasing networks • Broadened life experiences and skills

- 10.11 Harms are events or experiences that set back the interests of one or more individuals. Research may lead to harms, discomforts and/or inconveniences for participants and/or others. Researchers must consider the risk or likelihood of harm and the severity of its consequences as part of their consideration of the value of the research.

10.12 Although no list of harms is exhaustive, Table 2 identifies kinds of potential research harms that research participants may suffer. Note, however, that researchers must also consider the risks of harm to others, such as potential stigma to communities or groups. In addition, they must be aware of and plan to minimise potential harms for research personnel, such as the distress research assistants working with very sensitive data may experience.

Table 2: Summary of some potential harms for research participants

Category of harm	Potential harms
Physical harms	Injury, illness, pain
Psychological harms	Feelings of worthlessness, distress, guilt, anger or fear (eg, through disclosing sensitive or embarrassing information or learning about a genetic possibility of developing an untreatable disease)
Disrespect or harm to dignity (mana)	Devaluation of personal worth, including being humiliated, manipulated or in other ways treated disrespectfully or unjustly
Social or cultural harms	Damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation and findings of previously unknown paternity status
Privacy harms	Identification of private information
Economic harms	Direct or indirect costs to participants
Legal harms	Discovery of criminal conduct or being prosecuted for it
Data harms	Surveillance, inferential harm or social harms such as stigmatisation
Autonomy harms	Coercion, inducements, undue influence

10.13 Benefits and harms may be therapeutic or non-therapeutic in nature.

- Therapeutic benefit or harm arises from procedures used in research that will benefit or harm a participant in both clinical and research practice.
- Non-therapeutic harm or benefit occurs specifically in research practice from interventions and procedures that are solely undertaken to answer a particular research question. Such interventions are not undertaken with the intent of benefiting the individual patient, so the justification for any risk of non-therapeutic harm is that the research is expected to benefit future patients and society as a whole. Alternatively, in some instances, a non-therapeutic intervention can achieve contingent or incidental benefits. For example, additional blood sampling may identify something that is clinically relevant, but that is not the primary purpose of the intervention.

Minimal risk

10.14 A term that is often used to determine oversight in research activities is minimal risk. Minimal risk is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

The distribution of potential benefits and risks of harm

- 10.15 Having identified potential benefits and risks of harm, researchers must carefully assess the likelihood and potential severity of the risks of harm and burdens to individual participants and groups, in comparison with potential benefits that those participants or other individuals or groups may receive. When assessing research risks, researchers should consider whether to seek advice from others who have experience with the same methodology, population and research domain. They should also consider participants' perceptions of risks of harms and the potential for benefits.
- 10.16 Researchers must demonstrate a good understanding of the context in which a study is to be conducted. The context is especially important when the research offers direct benefits to the participants, their families and whānau, or particular groups, hapū or iwi with whom the participants identify. In such cases, participants may be ready to take on a higher risk of harm than they would otherwise. For example, people with cancer may be willing to accept research risks (such as treatment side-effects) that would be unacceptable to well people. Researchers should take such willingness into account in deciding whether the potential benefits of the research outweigh the risks of harm involved. For research interventions or procedures that offer no potential individual benefits to participants, the risks must be minimised and appropriate in relation to the social and scientific value of the knowledge.
- 10.17 Researchers must also consider the choices, experience, perceptions, values and vulnerabilities of different [populations of participants](#). A community's values and preferences are relevant in assessing potential benefits and risks of harm. Researchers should consult communities when determining if the potential benefits of a study are outweighed by the risks of harm or whether the balance is appropriate. The best approach is to follow a two-step process, looking first at potential harms and benefits to individuals, and then at potential harms and benefits to relevant groups.
- 10.18 No mathematical formula or algorithm can precisely calculate an appropriate ratio of benefit to risk of harm.²² Therefore, determining and evaluating the potential for benefit and the risks of harm may involve making intuitive judgements, which can be inconsistent and cause disagreement. The process must be transparent and defensible, and the results of the consideration clearly understandable.
- 10.19 Distributing potential benefits and risks of harm appropriately requires that:
- the benefits of research are distributed fairly and no group or class of people bears more than its fair share of the risks of harm from research participation
 - the research does not disproportionately focus on the health needs of a limited class of people, but instead aims to address diverse health needs across different classes or groups. For example, where the under-representation of particular groups results in or perpetuates health disparities, equity may require special efforts to include members of that group in research
 - groups that are unlikely to benefit from any knowledge gained from the research should not bear a disproportionate share of the risks of harm of research participation
 - individuals, communities or populations that are socially or economically disadvantaged or marginalised are not over-represented in or unfairly exposed to risk of harms in research, or denied access to the research benefits.

²² Ridd.

- 10.20 When potential benefits or risks of harm are to be distributed unequally among individuals or groups, researchers must scientifically and ethically justify the criteria for unequal distribution rather than choosing them arbitrarily or conveniently.
- 10.21 Where the potential benefits do not justify the risks of harm in a research proposal, the researchers must reconsider the research aims or the methods proposed to achieve those aims, or both.

Managing and minimising risks of harm

- 10.22 In designing a study, researchers have an obligation to minimise risks of harm to participants, and manage any residual risks. Minimising risk involves assessing research aims and their importance, and identifying the safest methods of achieving them.
- 10.23 Managing risks includes ensuring that:
- participants clearly **understand** the risks of harm associated with the research
 - **mechanisms** are in place to adequately identify and manage any harms that may occur at any time during the research, and these measures are specified in the research protocol.
- 10.24 Managing the risks of harm must continue throughout the study. Where available data demonstrates that the risks of harm outweigh the potential benefits or establishes clear evidence for or against the research interventions and procedures in the study, researchers must assess whether to continue, modify or immediately stop the study.
- 10.25 The research protocol should document the processes for minimising and managing risks of harm. Researchers should submit those processes to the appropriate ethics committee for review.

11 Research development and design

Introduction

- 11.1 For research to be ethical, it must be well designed and the research question must have the potential to lead to improvements in health and wellbeing. Well-designed research is scientifically robust and uses a research methodology that takes account of relevant cultural, social and economic factors.
- 11.2 Tika provides a general foundation for tikanga Māori (indigenous ethics). In the Māori context, it refers to what is right and what is good for any particular situation. In this framework, it is related to the validity of the research proposal. The design of a research study is critical in determining whether the research achieves its proposed outcomes, benefiting participants and communities.

Standards

- 11.3 The study design must be appropriate to answer the research question.
- 11.4 Research must be conducted according to a suitably detailed protocol.
- 11.5 Research should not exclude participants on the basis of their age, disability, sex, gender, ethnicity, nationality, religion, education or socioeconomic status, except where excluding or including them on these grounds can be justified for the purposes of the research.
- 11.6 The researchers involved must have the necessary skills and resources to undertake the research.
- 11.7 One or more individuals with appropriate disciplinary and cultural knowledge, skills and experience must review the research. Reviewers must be impartial to and independent of the research.

Commentary

Design

- 11.8 Only appropriately designed research will justify the risk of harm, inconvenience or resource allocated to it. The study design has a strong impact on whether the study meets its objectives. It also influences the study methods, conduct, costs, outcomes, interpretation and potential for translation of findings into practice.
- 11.9 Research that is methodologically sound will meet generally accepted requirements for the subject matter, the population under study, and the research method and analysis. Internal validity, reliability, generalisability and translatability of study methods and results are important aspects of the study's scientific value.

Protocol

- 11.10 A research protocol is a document that details the plan for conducting a study, including its purpose and how the research will be conducted. This information helps demonstrate that the researcher has considered and addressed the ethical and scientific or methodological issues associated with the study.
- 11.11 Protocols must include all relevant information. At a minimum, all research protocols should include:²³
- the study title
 - the principal researcher, study site(s) and sponsor
 - a literature review summarising existing knowledge and highlighting gaps in knowledge
 - a clear statement of the justification for the study, including expected benefits and merit of the research, as well as how they outweigh the harms
 - a summary of the proposed research
 - a description of the ethical and regulatory aspects, including ethical risks and considerations raised by the study, and how it is proposed to deal with them
 - the study hypotheses or objectives
 - the main outcome(s) of interest
 - a detailed description of, and clear justification for, the study design
 - a clear and ordered plan of study conduct
 - criteria for including or excluding potential participants and justification for these
 - criteria for terminating the study, if appropriate
 - what data will be collected, stored and used and how this data will be collected, stored, used and kept private
 - the number of participants required to achieve study objective(s) and how the study identified this through planned statistical analysis
 - an analysis plan appropriate to the study design
 - how the study results will be shared publicly and communicated to participants as appropriate
 - any partnership arrangements with whānau, hapū and iwi
 - actual or potential conflicts of interest and how they will be managed.

Research population

- 11.12 All groups have the right to benefits from advances in health care and disability support arising from research. For this reason, it is important that researchers design their

²³ For further information on developing and designing protocols, please see:

- the Spirit Group's website (www.spirit-statement.org)
- the CIOMS (2016) [guidelines](#) which contain a complete list of items to include in a research protocol
- the Equator Network's website (www.equator-network.org), which has useful templates and practical guides for different types of study.

research to be inclusive. A study's focus and objectives, and the nature and context of the research, should determine its inclusion and exclusion criteria.

- 11.13 Research circumstances may mean that potential participants could be vulnerable in the context of the study and limit their ability to fully safeguard their own interests. However, researchers should not automatically consider individuals to be vulnerable based only on their assumptions about the vulnerability of the group to which those individuals belong. Researchers should recognise and address changes in a participant's circumstances that may create, heighten or lessen their vulnerability. See Chapter 8 for more information on [vulnerable groups and individuals](#).
- 11.14 Inclusion and exclusion of participants affect the extent to which researchers can generalise their findings. By including all those to whom the research findings may apply, researchers contribute to an equitable distribution of research benefits and burdens. This is important to ensure the expected merit of the study can be achieved.

Equal explanatory power

- 11.15 Equal explanatory power refers to the power of research to generate findings and to offer explanations that are specific to Māori participants and their communities.
- 11.16 In quantitative research of the general population, such as population surveys, this approach may require oversampling Māori participants in order to achieve equal statistical power for Māori and therefore produce information to improve Māori health to at least the same depth and breadth as non-Māori health. Historically, research has typically involved a representative population sample (that is, approximately 15 percent Māori and 85 percent non-Māori), or even undersampled for Māori due to inappropriate and/or ineffective methods of encouraging Māori participation (such as using only postal questionnaires written in English). The conclusions and recommendations from such research therefore favour the rates or views of the numerically dominant non-Māori.
- 11.17 Equal explanatory power in both quantitative and qualitative research in New Zealand is important to prevent research conclusions from contributing to increasing inequality.

Exclusion criteria

- 11.18 Exclusion criteria are not the inverse of the inclusion criteria. Instead, they identify individuals who meet the inclusion criteria but cannot be included in the study for some other reason. Exclusion reduces the generalisability of study results. Exclusion is justifiable when inclusion poses potential safety concerns to participants or their inclusion may impact on scientific validity.
- 11.19 Overprotective attitudes or practices of researchers can exclude members of some groups in society from participating in research. If knowledge about the health experiences and needs of these groups is to advance, they may need to participate in research in appropriate ways, so researchers should give special considerations to including them in their research.

Researchers' skills and resources

- 11.20 Researchers must be suitably skilled and resourced (or, if appropriate, be supervised by an appropriately skilled and resourced person) to minimise risk to participants and realise

any potential benefits of the study. Researchers must also have adequate facilities, time and resources available to conduct the study safely and in the intended timeframes.

11.21 Appropriate skills and resources may include:

- being competent in the field of research and research methods, as demonstrated by knowledge, qualifications, experience and current awareness of good practice guidelines
- having experience in identifying and applying relevant research methods, with the ability to take full responsibility for proper research design, conduct and analysis
- appreciating the research context and environment, including understanding different community and cultural views
- understanding the inequalities in health and wellbeing of populations, in particular those experienced by Māori
- having the ability and resources to monitor participants throughout the research
- knowing researchers' ethical responsibilities and demonstrating ethical principles
- being able to suitably protect confidentiality and data security
- having appropriate skills and resources to deal with unexpected events that may affect participants and/or researchers
- working in a suitable research setting (eg, with qualified staff and appropriate infrastructures for safe and ethical conduct)
- having an appropriate budget to allow researchers to complete their study in a timely way
- having appropriate indemnity cover
- having the capacity to disseminate and communicate research findings.

Peer review

11.22 Peer review should address the validity and feasibility of the design, methods and analysis of the study. Additional specialist (eg, statistical, economic, cultural or analytical) review may be required. Peer review may include considering cultural relevance and appropriateness.

11.23 All research proposals should be peer reviewed in a way that is fit for purpose and proportional. Suitable reviewers will have appropriate expertise and an appropriate skill set. Involving more than one reviewer may also be appropriate. Reviewers must be sufficiently independent to be able to conduct their review of the study without bias.

11.24 Researchers should give peer reviewers sufficient details of the proposed study for them to consider the scientific validity of the study. Commercial sensitivity is not an acceptable justification for failing to seek independent review. Reviewers should also consider the ethical aspects of the study. Studies can be of satisfactory scientific quality, as judged by peer review, but still pose ethical concerns.

11.25 For more information on peer review, see the Committee on Publication Ethics (2017) [guidelines](#).

12 Types of studies

Introduction

- 12.1 These standards broadly categorise research as interventional or observational, while noting that many studies contain elements of both. The type of study researchers choose for their research should be the one best suited to answering the study question while meeting ethical standards.

Standards

- 12.2 Researchers should conduct initial tests of a new intervention under lower-risk conditions before escalating to higher-risk study conditions, even if the new intervention is likely to be more therapeutically beneficial for a higher-risk population.
- 12.3 A non-therapeutic intervention study, or an invasive means of collecting data in an observational study, is justified only when the importance of the objective outweighs the inherent risks and burdens to the participant and when participants are well informed of these risks.
- 12.4 Participants enrolled in therapeutic intervention studies should have post-study access to the best-proven intervention, where such an intervention is available.
- 12.5 Studies comparing two or more interventions should meet the standard of equipoise, in which the expert medical community is genuinely uncertain as to the overall balance of risks and benefits between the interventions offered in the study.
- 12.6 Participants in the control group of an interventional trial should receive an established effective intervention, unless researchers can ethically justify a different approach. The choice of control must be appropriate for participants and study design.

Commentary

Observational studies

- 12.7 Observational studies are distinguished from intervention or experimental studies in that the researcher does not influence the assignment of any variable in an observational study. Instead, the researcher observes and analyses natural relationships between variables and outcomes and records them.
- 12.8 Observational studies include case control studies, cohort studies, cross-sectional studies, case reports, case series and descriptive studies. The prospective collection of data – such as from blood samples, imaging or questionnaires – does not change a study from observational to interventional. Observational studies are not automatically of minimal risk; indeed, they may involve invasive or high-risk means of collecting data from participants.

- 12.9 The method of data collection may increase the risk of harm to those whose health information is used. The potential for privacy or data harm, for example, is a significant consideration in observational studies. Such risks of harm must be rigorously identified, gauged, **minimised and managed**.

Intervention studies

- 12.10 In an intervention study, the researcher controls and studies the intervention(s) that they provide to participants for the purpose of adding to knowledge of the health effects of the intervention(s). The term ‘intervention study’ is often used interchangeably with ‘experimental study’.
- 12.11 Close ethical scrutiny is appropriate for intervention studies because the potential harms may be greater than with other types of study.
- 12.12 An intervention study may evaluate:
- a preventive, diagnostic or therapeutic intervention (including medication, psychological treatment, health education, radiation therapy, a vaccine, a surgical device or a surgical or other technique)
 - a new intervention
 - an intervention established in practice but not adequately substantiated by scientific evidence
 - an established intervention being used for a new purpose
 - the withholding or altered administration of an established intervention
 - a change in the method of delivering care (eg, the use of directly observed therapy for the treatment of tuberculosis as opposed to patient-administered medication, a new model of care, use of guidelines or protocols, use of different information formats, or care undertaken by a different group of professionals).
- 12.13 A randomised controlled trial is often the best way of addressing questions about the effectiveness of treatments or preventions. Such a trial allocates participants to the intervention arms in a way that minimises the influence of confounding factors (variables that influence both the dependent variable and independent variable, causing a spurious association).
- 12.14 Studies must be scientifically sound in order to be ethical. Scientific integrity of a randomised controlled trial requires that the researcher design and conduct it in a way that minimises systematic error (bias). They should give particular attention to the means of randomisation, allocation concealment, blinded outcome assessment (where feasible), sample size and completeness of the analysis population.

Risks of harm in intervention studies

- 12.15 Potential harms to individual participants in intervention studies can include physical harms such as adverse events or lack of efficacy from the intervention, psychological harm, or harm from receiving a placebo. At a community level, potential harms may involve placing an inequitable burden on a community without offering it a corresponding benefit. Sometimes the benefits in an intervention study accrue to one group of individuals while the harms are experienced by a different group.

Therapeutic and non-therapeutic studies

- 12.16 In a therapeutic study the researcher has a reasonable expectation that the intervention under investigation may benefit study participants. In contrast, in a non-therapeutic study researchers have no such expectation; instead, they are conducting the study to gain knowledge that may contribute to the future development of new treatments or procedures. It is particularly important that researchers minimise the potential for harm in non-therapeutic studies, where participants have no opportunity to benefit from the intervention provided.

Incremental testing in early-phase trials

- 12.17 By escalating risk incrementally through their testing, researchers can refine and test techniques in the safest possible manner. This approach also helps them to minimise the prospect of catastrophic events that might harm participants and undermine confidence in development of interventions. Researchers should justify dose level, dose escalation and cohort size in relation to international best practice.
- 12.18 Researchers should use methods such as sentinel dosing along with careful safety monitoring to protect participants from unnecessary risks.

Access to an intervention after the study

- 12.19 Participants who benefit from a study intervention during the intervention should ideally have ongoing access to the study intervention for as long as it is clinically beneficial. Although in most intervention studies no one knows which intervention is best until after the study has been completed, researchers must clearly explain to all participants the arrangements for access after the study, including any uncertainties about that access. The sponsor and researcher should also seek access to effective interventions for study and target populations in discussion with relevant authorities.

Equipoise

- 12.20 An intervention study meets the equipoise standard if the evidence is 'equally poised' as to the overall balance of risks and benefits of each of the interventions offered in the study. As a result, no one can establish in advance which of the groups in a proposed study will be better off through participating in the research.
- 12.21 For any study comparing two or more interventions, researchers should design it to meet the equipoise standard. They should not randomise or assign study participants to different interventions when available evidence demonstrates that one intervention has a better expected overall balance of benefits over risks than the other(s). However genuinely felt, an individual feeling of certainty or uncertainty is not enough to demonstrate the presence or absence of equipoise. It may be justifiable to randomise participants to study arms that are not in equipoise if the better arm is not available as part of standard care and can only be offered to participants, by chance, in the intervention study.

Controls

- 12.22 Using controls in clinical trials may create the potential for conflict between the demands of sound science and the obligation to safeguard the health and welfare of study participants. Controls in clinical trials can include a placebo (an inert substance or sham procedure used with the goal of isolating the clinical effects of the investigational intervention) or an active control (where the investigational intervention is compared with an established effective intervention).
- 12.23 In general, researchers should design studies to generate accurate scientific information without delaying established effective interventions for or withholding them from participants. Established effective interventions may include interventions that, while not necessarily the best proven intervention, are professionally recognised as reasonable options. Researchers who propose to delay or withhold established effective interventions must provide compelling justification for this. They must fully inform participants of treatments available to them outside the study and how these differ from study participation.
- 12.24 The risks of a placebo control are typically very low (eg, ingesting an inert substance) but occasionally can be considerable (eg, undergoing a sham procedure such as surgical incision under general anaesthesia). Researchers must consider and minimise risks associated with placebos. They may use a placebo as a control when:
- the study is non-therapeutic (ie, the intervention under study is not expected to benefit participants)
 - no established effective intervention is available for the condition under study
 - all participants receive an established effective intervention and are then randomised to receive the addition of the study intervention or placebo
 - in cases where there is an established effective intervention:
 - delaying or withholding the established effective intervention will result in no more than a minor increase in risk to the participant (and risks are minimised) and
 - there are compelling scientific reasons for using only a placebo and withholding the established effective intervention.
- 12.25 Compelling scientific reasons for placebo controls may exist when a trial cannot distinguish effective from ineffective interventions without a placebo control. Examples of 'compelling scientific reasons' include that the:
- clinical response to the established effective intervention is highly variable
 - symptoms of the condition fluctuate widely
 - condition under study is known to have a high response to placebo
 - rate of spontaneous remission of the condition under study is high.
- 12.26 Researchers must decrease the period of placebo use to the shortest possible time that is consistent with achieving the scientific aims of the study. They may reduce the risks by permitting the placebo arm to change to active treatment ('escape treatment'). The protocol should establish a threshold beyond which the participant should be offered the active treatment.

Epidemiological and public health research studies

- 12.27 Epidemiological and public health research studies often involve use of different study methods and tools on a large number of research participants in single or multiple settings. Many include features of observational studies (such as cross-sectional studies), case control studies, cohort studies, case reports, case series and other descriptive studies, as well as features of intervention studies (such as field trials and cluster randomised controlled trials, stepped-wedge and quasi-experimental study designs involving groups, geographic areas, institutions or systems collectively rather than individually).

Ethical issues in newer trial designs

- 12.28 Although randomised controlled trials remain the gold standard for evaluating new treatments for disease, innovative trial designs are emerging that may present new ethical challenges.

Co-design or participatory research designs

- 12.29 Co-design or participatory research designs involve a mutually advantageous collaboration from the early stages in question framing, research design, delivery, implementation and dissemination between researchers and participants who may also be the end-users of research discoveries. The emergent nature of such action research designs means that it is difficult to specify the study interventions or measures, or the roles of participants in advance. This methodology raises distinct ethical challenges for researchers (and ethics committees), for example with regard to power imbalances, especially when compared with more traditional designs that involve gaining informed participant consent (and ethics committee approval) for all study processes up front.
- 12.30 Researchers should therefore justify why the co-creation approach is likely to maximise the impact and minimise the harms of the research, and should identify which of the study features are likely to be integral and stable components of the research, and which will subject to openness and co-creation with community partners. Researchers should also be explicit about the potential benefits of power sharing in terms of reducing inequalities and empowering vulnerable communities, and should have a developed plan for managing the relationships between themselves and their participants in ways that are likely to achieve these benefits. Establishing a cooperative relationship with the ethics committee responsible for safeguarding participants' safety and welfare, and making staged applications are also recommended.

Adaptive design trials

- 12.31 An adaptive design trial includes an opportunity planned in advance to modify one or more specified aspects of the study design and hypotheses based on analysis of data (usually interim data) from participants in a study. Researchers analyse the accumulating study data at pre-set times within the study, with or without formal statistical hypothesis testing. The adaptation process generally continues throughout the trial, following the trial protocol. Modifications may include changes to dosage, sample size, intervention(s) undergoing trial and patient selection criteria. Importantly, the trial protocol is set before the trial begins, specifying the adaptation schedule and processes.

- 12.32 Oncology umbrella trials, basket designs and platform trials are increasingly using adaptive study designs. Umbrella trials allocate treatment for a single tumour type from a pool of treatment possibilities, according to participant biomarkers. Basket trials allocate differing tumour types with shared biomarkers to a common treatment. Both designs can include rules for adding or dropping treatment arms.
- 12.33 Adaptive platform trials may simultaneously investigate multiple categories of treatment for a single complex condition. By adding or dropping options within a category depending on analysis of interim results, researchers can investigate the possibility of synergy between treatments in a timely manner that is not possible if each combination is the subject of a single trial.
- 12.34 Adaptive trials have the potential to reduce participants' exposure to ineffective treatments, hasten treatment development, conserve research resources and increase the likelihood that the trial will deliver a clinically useful result.
- 12.35 There are questions about how such complex designs meet the substantial evidence standard required for new drug approvals, for example. At the same time, adaptive trials create ethical challenges. Significant ethical issues may concern equipoise (given that randomisation rates may change throughout the study as one arm is shown to be more beneficial) and informed consent (because this kind of study is difficult to explain to participants). Safety monitoring and statistical analyses are also especially important in this kind of study design and researchers need specific expertise to perform them well.
- 12.36 There are several steps that researchers may take in advance of initiating an adaptive clinical study. These include:
- clearly describing the adaptive nature of the study in the protocol
 - crafting an informed consent document that accurately reflects the study's risks, and meets other informed consent requirements, including describing the adaptive nature of the study in lay language
 - potential planned adaptations and the circumstances under which protocol amendments will be submitted for review must be described to the ethics committee.

Cluster randomised trials

- 12.37 Cluster randomised trials (CRTs) involve randomly allocating groups of individuals or clusters such as communities, hospitals or medical practices to different interventions. CRTs pose distinct ethical challenges for several reasons. For example:
- the units of allocation, intervention and outcome measurement may differ in a single trial
 - some interventions can affect the interests of many individuals associated with a cluster, including those remote from the study
 - clusters are randomised before it is possible to identify and recruit individuals for informed consent
 - study interventions may be difficult or impossible for individuals to avoid, so that they cannot meaningfully refuse to participate in the study
 - the study targets social groups or organisations as the units of allocation, but current understanding of the moral status of such groups is incomplete
 - vulnerable subgroups within clusters may be difficult to identify.

- 12.38 As in all health research, all individuals whose interests are affected by study interventions or data collection procedures are considered to be research participants, and researchers must identify all of the participants in their CRT. These include all those who are the intended recipients of experimental (or control) interventions (including environmental manipulations) and those from whom the researcher intends to collect personal health information. Participants may be patients or health care workers, or both. For example, in CRTs that target interventions to health care workers (eg, an alternative hand-washing protocol), researchers may use aggregate data from patients' records to judge the effectiveness of the intervention.
- 12.39 Having the requirement to get consent from health care workers who researchers will observe or who will apply a different health care method can confound or compromise results or make it difficult to analyse the data collected. However, researchers must get informed consent from all participants in a CRT. This is because under New Zealand law there is no legal mechanism to waive consent for research participants who can provide their own consent, even if the study design means that obtaining individual informed consent is impracticable or not feasible. In such cases, [integrated consent](#) may facilitate recruitment for CRTs. Researchers must pay special attention to recruitment, privacy and consent procedures for participants who are less able to freely consent due to their position in the cluster or hierarchy.
- 12.40 When a study involves a group or community whose interests are substantially affected by the CRT, researchers should consult with representatives of the groups to inform study design, conduct and reporting and to get their agreement to the study. Such permission does not replace the need to get informed consent from all of the individual participants.

Pragmatic comparative effectiveness research

- 12.41 Comparative effectiveness research (CER) compares established treatments when existing evidence is insufficient to determine which has the superior balance in terms of efficacy and safety. Researchers considering CER design must first thoroughly assess the range and quality of published evidence to identify existing knowledge, along with points of uncertainty and disagreement. The trial design should respond to these disagreements by gathering additional evidence that may permit researchers to differentiate between treatments and identify specific group(s) to whom the treatments should be applied.
- 12.42 Researchers must also clearly distinguish any specific risks associated with randomising individuals to one or other trial arm from the risks reasonably expected from assigned clinical treatment. Researchers must plan to minimise these risks by strategies such as:
- restricting participants to a particular group, either by using explicit inclusion and exclusion criteria or by allowing participants to self-select their group based on information provided to them before they agree to take part in the research. Decisions about criteria should be based on a thorough analysis of expert views
 - introducing risk reduction strategies, such as increased monitoring, as part of the clinical trial itself.

- 12.43 CER designs must uphold the other ethical standards for conducting clinical research described in this publication. These standards include that participants:
- must give voluntary and informed consent to participate in the study, which may be justifiable as an [integrated consent](#).
 - should clearly understand the extent to which their health information will be used in research, including whether data will be harvested in the future
 - must receive clear, non-technical explanations about any differences (including differences in relative risk) between being randomised to a study arm by chance and the alternative of not participating in the trial – that is, receiving the treatment chosen by their provider or determined by institutional guidelines.

13 Research conduct

Introduction

- 13.1 Responsible research conduct involves an enduring commitment to carrying out investigations with integrity. Researchers must be aware of established professional standards and ethical principles and apply them in performing all study activities. Conducting research responsibly is critical to achieving research excellence, as well as to maintaining public trust in health care. This chapter focuses on the essential aspects of responsible research conduct in relation to participants.

Standards

- 13.2 The principal researcher of a study has primary responsibility for the conduct of the study (including compliance with relevant law, regulations and guidelines) in New Zealand.
- 13.3 Researchers have a primary duty of care to participants throughout the life cycle of a study.
- 13.4 Researchers must choose a method of selecting and approaching participants that both is appropriate for the study and avoids unduly influencing potential participants.
- 13.5 Any incentives offered should not unduly influence an individual's decision to participate. Researchers should determine the value of incentives in a transparent way. Similarly, Researchers should ethically justify any costs to participants to an ethics committee, ensuring that discrimination is avoided and recruitment is fair.
- 13.6 Researchers should identify and minimise any conflict of interest or commitment (or perception of such conflict).
- 13.7 Researchers must have a plan for monitoring and reporting the safety of participants. The level of safety oversight must be appropriate to the study phase, design and cultural context.
- 13.8 Researchers must promptly report new information that may affect the safety or ongoing consent of participants to appropriate regulatory bodies and to participants.
- 13.9 Researchers must report their research results accurately, with integrity and in a timely manner, whether those results are positive or negative.
- 13.10 Research results must be released in a way that recognises cultural sensitivities, avoids stigmatising individuals or groups and does not identify individual participants without consent.
- 13.11 Researchers must offer participants a summary of research results that is written for non-specialists in plain language.
- 13.12 Researchers should register their study in the Clinical Trial Registry. They should also provide results of the study in the public database of the Clinical Trial Registry.

Commentary

Overall responsibility for the study

- 13.13 While it is an essential duty of research institutions to educate people on how to conduct research responsibly and ethically, the primary researcher is responsible for the conduct of his or her study.

Whakapapa

- 13.14 Whakapapa is used to explain both the genesis and the purpose of any research kaupapa (topic or purpose). Whakapapa is an analytical tool for understanding why relationships have been formed and for monitoring how the relationships progress and develop over time (mai i te whāi ao ki te ao mārama). In the context of decision-making about ethics, whakapapa refers to the quality of relationships and the structures or processes that have been established to support them. The development and maintenance of meaningful relationships between researcher and research participant is an indicator of the ethical tenor of a study.²⁴
- 13.15 Researchers must safeguard the health and welfare of participants during the study. They must also ensure the participants experience no gaps in care when their study participation concludes.

Recruitment methods

- 13.16 Many methods of recruiting participants are available. It is important the chosen method is appropriate for the potential participants and the study. In determining appropriate recruitment methods, researchers should consider:
- the characteristics of participants they are seeking to recruit
 - the research methods they intend to use
 - the acceptable practices of any relevant professional bodies or academic disciplines.
- 13.17 All recruitment efforts must respect personal rights to privacy and confidentiality, comply with health information privacy regulations and avoid unduly influencing participants.
- 13.18 The same standards apply if a patient (or their family or friends) approaches their health practitioner or a researcher about participating in a study.

Charging participants

- 13.19 People who are already burdened by poor health are in general [a potentially vulnerable group](#). Asking them to contribute considerable sums in exchange for being involved in research raises serious concerns about justice, autonomy and the potential for exploitation. Researchers may be able to justify charging participants to receive trial products or procedures in a very limited set of circumstances. Among those circumstances are that:

²⁴ For more information see Hudson et al. 2010. Te Ara Tika Guidelines for Māori research ethics.

- researchers have explored all options to raise funds for the research
- the research has a very high likelihood of generating benefit to the worst-off in society in the long run
- charging participants does not compromise the [study design](#), especially with respect to blinding, [randomisation](#) and sample size
- extra safeguards against [therapeutic misconception](#) are in place: those who ‘pay to play’ are paying to participate in a study that aims to provide social value through generalisable knowledge. They are paying to be involved in research, and any potential benefit to the participant is merely an unlikely side effect
- evidence indicates the trial products or procedures have a potential clinical benefit that would provide a significant advantage over available products or procedures in the diagnosis, treatment, mitigation or prevention of a disease or condition
- the research cannot be conducted without charging.

Identifying potential participants

13.20 Effective recruitment is critical to enrol a sufficient number of participants to allow researchers to reliably answer the study question(s). To select study participants, the researcher must use a fair, equitable process and include ethnic, educational, socioeconomic and gender diversity appropriate to the health condition under study.

13.21 It may be ethically justifiable for clinicians and other health care providers involved in a patient’s care to use their records to identify or pre-screen potential research participants. The benefits of reviewing records in this way are that researchers can be sure that those they approach are eligible and that they do not expose individuals to risks unnecessarily. They may use this method provided that:

- the sole purpose of the record review is to identify prospective research participants
- the patient information to be reviewed is restricted to only the information that is necessary to identify prospective participants for the study
- the number of people who have access to identifiable information is minimised
- neither the patient records nor any identifiable information is copied or removed from a secure location, except for the minimum information necessary to contact a potential participant.

13.22 In some cases, a researcher who is not involved in treating the patients may wish to review records or obtain lists of other physicians’ patients, medical records, test results or other clinical information so that they can approach potential participants. To do so, such a researcher must be able to justify how the review of records is ethical [without gaining the consent](#) from the individuals linked to those health records.

Approaching potential participants

13.23 Depending on the study question and design, the researcher may approach the potential participant directly (eg, by advertisement, telephone or letter) or indirectly (eg, through the participant’s own doctor or relevant health professional).

- 13.24 The person who contacts potential research participants should be knowledgeable about the study, and able to discuss study details and answer questions in plain language. When patients are recruited as prospective participants, the people directly involved in their care should make the first approach, rather than researchers they do not know. In limited circumstances, it may be justifiable for both the researcher and the health care provider to make the first approach (ie, in a joint letter) or for the researcher to do so with reference to the health care provider.

Advertising

- 13.25 Advertisements seeking participants for a study should not inflate the potential benefit of participation or imply that a health outcome is certain. The design of recruitment advertisements must avoid deceiving or unduly influencing potential research participants.
- 13.26 The information provided in advertisements should be limited to basic study information written in plain language. It may include:
- an accessible title for non-specialists
 - the study's purpose
 - eligibility criteria
 - study procedures
 - location
 - time or other commitment required of participants
 - the person or office to contact for further information.
- 13.27 Researchers should avoid eye-catching visual cues and obscure language that may cause potential participants to underestimate or dismiss their risk of harm. They should also avoid statements that appeal to heroism or bravado such as 'Help advance health care!'
- 13.28 Advertisements should not highlight or emphasise study remuneration, especially when potential participants are vulnerable to financial incentives.

Social media

- 13.29 Recruitment through social media has novel aspects compared with other recruitment methods in that it involves:
- following website policies and 'terms of use'
 - recruiting from the social networks of current or potential participants
 - managing online communication from and between participants.
- 13.30 Researchers should examine the terms and conditions of websites, considering:
- the degree to which the social media venue is public
 - whether the site places restrictions on its use for recruitment or research
 - whether tracking and data mining activities are publicly disclosed to potential users before they join

- what types of interactions are expected and tolerated on the site, how personal information shared over the site may be used, and who will have access to that information and for what purposes, among other contractual expectations.

- 13.31 The following are general guidelines on recruiting through social media.
- 13.32 Researchers should not disclose sensitive information to others without the participant's explicit permission, or engage in online interactions that would allow others to infer sensitive information about participants or potential participants. They should avoid such disclosure even if that information has already been made public in a different context.
- 13.33 Researchers should be mindful of the values, mores and potential vulnerabilities of people they approach on social media.
- 13.34 Researchers must be transparent in their use of social media for active recruitment. They must avoid **deception** and refrain from fabricating online identities to gain access to online communities. They should seek access through alternative means, such as asking for explicit permission from a moderator or site administrator.
- 13.35 Researchers should avoid covert surveillance for the purposes of identifying potential participants on a site where users reasonably expect that recruitment activity will not occur and could justifiably object to such activity.
- 13.36 Researchers should get authorisation from current or potential research participants before using their online network for recruitment purposes, or to enlist current or potential participants to approach members of their network directly on the research team's behalf. Exceptions to this requirement may be justified in situations where the researcher independently identifies the relevant individuals for study recruitment without using the online network of the current or potential participant.

Reimbursements, koha and incentives for participants

- 13.37 In considering the possibility of undue influence in research involving financial or other incentives, researchers should be sensitive to issues such as the economic circumstances, age and capacity of prospective participants, the customs and practices of the community, and the magnitude and probability of harms.
- 13.38 Researchers may seek to create legitimate motivation for people to participate in studies, but must not exert undue influence by offering inappropriate incentives. Conversely, they should take care to avoid causing undue financial disadvantage to participants, such as travel costs and parking charges.
- 13.39 Researchers should state at the outset of the study in what circumstances participant withdrawal will affect payments, including koha, and what that effect will be.

Managing conflicts of interests or role conflict

- 13.40 A conflict of interest can be any situation in which the possibility of financial, professional or other personal gain has the potential to compromise a researcher's professional judgement and objectivity. This may occur during study design, conduct or reporting. Unmanaged conflict of interest may harm study participants, particularly in clinical research, and damage the research enterprise by reducing the trust and confidence that people generally have in research.

- 13.41 Researchers must identify conflicts of interest (real, potential and perceived) and then manage, reduce or eliminate them. They must assess conflicts of interest in terms of both their likelihood and their consequences. If a conflict is to be managed properly, disclosure must be full and prompt and all appropriate safeguards put in place, such as modifying the research plan or arranging for independent monitoring.
- 13.42 While financial conflicts of interest are the most visible and measurable type of conflict, other types can have a powerful influence. Conflicts of commitment involve two sets of professional obligations competing for focus and effort when an individual has multiple roles, for example as both a health care provider and a researcher.
- 13.43 Conducting research on one's own patients can be a legitimate way of creating knowledge.
- 13.44 However, dual-role researchers can face several significant ethical challenges in terms of undue influence, compromising the voluntary nature of participation, informed consent and privacy. Some options for managing these issues are:
- including patients that are in the care of another health care provider
 - using an independent person to explain the study and obtain consent
 - recognising the conflict and declaring it, and mitigating risks to [informed consent](#).

Monitoring studies

- 13.45 Every study requires a safety monitoring plan. The degree of monitoring and oversight required depends on the study's particular features. This section outlines different types of monitoring arrangements and when each one is suitable.
- 13.46 Any safety monitoring plan should include a mechanism by which researchers may remove participants for safety reasons. It should also provide a way of stopping or amending clinical trials if they are found to be unsafe, futile or ineffective. Mechanisms for safety monitoring include trial oversight committees, a trial coordinating centre and on-site monitors.

Trial oversight committees

- 13.47 Trial oversight committees may include one or more of the following.
- **A trial steering committee** provides overall supervision of the trial and ensures that it is being conducted in accordance with the principles of good clinical practice. It may have members who are independent of the researchers.
 - **A trial management group**, which should be in place for every trial, is responsible for the day-to-day management of the trial. Members often include the statistician, the trial coordinator, the data manager and the research nurse(s); however, in small, simple studies this 'group' may comprise just the principal researcher.
- 13.48 **A data monitoring committee (DMC)** exists to protect the safety of the study participants, the credibility of the study and the validity of the study results. A DMC is an advisory body responsible for monitoring emerging safety and efficacy data, reviewing trial conduct and making recommendations to the trial steering committee and study sponsor(s). Normally, the DMC should have sole access to the data emerging in the study. The DMC recommends ending a study early if it produces convincing evidence of benefit or unfavourable results ruling out benefit, if safety concerns arise or if the

probability of the trial achieving its objectives is low. Where the risks of a study are low, it may be appropriate to have no DMC. It is generally an independent body, although in some circumstances it may be internal to the study, including representation from the trial steering committee and/or the study sponsor.²⁵ Table 3 indicates the most appropriate form of DMC monitoring for different types of intervention studies. Members of the DMC, especially the chair and the biostatistician, should have prior DMC experience.

Table 3: Forms of DMC monitoring for different types of intervention studies

Appropriate form of DMC monitoring				
Type of setting ¹	Imperatives		Need for DMC	
	Ethical integrity	Credibility	Independent DMC	Internal DMC
Setting 1				
Randomised trials (phases IIb, III, IV)	Yes	Yes	Yes	Likely ²
Randomised trials (phases I, IIa)	Yes	Likely	Maybe	Likely ²
Non-randomised trials	Yes	Maybe	Unlikely	
Setting 2				
Randomised (any phase trial)	Unlikely	Likely	Unlikely ³	Maybe ²
Non-randomised	Unlikely	Unlikely	No	Unlikely

- 1 Setting 1 includes: life-threatening diseases (treatment, palliation and prevention); diseases causing irreversible serious morbidity (treatment, palliation and prevention); novel treatments for life-threatening diseases (treatment, palliation and prevention) with potential for significant adverse events; and vulnerable populations. Setting 2 includes trials not included in setting 1.
- 2 An internal DMC would be advised if an independent DMC is not established.
- 3 Integrity/credibility issues could motivate use of an independent DMC; for example, if a trial in this setting were to impose interim monitoring of comparative data.

Coordinating centres or database monitoring

13.49 A trial coordinating centre monitors data as it enters the database during the trial. This monitoring includes: checking the data against the protocol and for internal logic; and checking eligibility, recruitment rates, withdrawals, missing data and loss to follow-up. The centre should monitor all trials to ensure integrity of study data.

On-site monitoring

13.50 Monitors visit study sites to check adherence to study protocol and good clinical practice guidelines. Their monitoring normally includes checking informed consent and eligibility, checking data on study case report forms against source data, and checking adverse event reporting. The extent of on-site monitoring that is appropriate depends on factors such as the degree of risk, the complexity of the study, blinding and the experience of sites.

²⁵ For further guidance about operating plans for DMCs please visit www.hrc.govt.nz.

Responsibilities for adverse event monitoring

- 13.51 The protocol and/or monitoring plan of any intervention study should state the processes and responsibilities for identifying, coding, analysing and reporting adverse events. To reliably interpret adverse events, it is necessary to code them according to body system and severity using established systems, and compare grouped data across intervention arms (considering the benefit and risk profile). See Table 4 for definitions of key terms in adverse event monitoring.
- 13.52 Prompt reporting of serious adverse events is especially important for suspected unexpected serious adverse reactions (SUSARs).
- 13.53 Every study should have a mechanism in place for responding to any potential safety concerns. In general, reliable interpretation of the safety signals would require an interim report on safety and efficacy, in a form unblinded by intervention arm. Any intervention study with potential for serious treatment-related adverse events should have a mechanism in place for promptly reporting, recognising and responding to serious adverse events and SUSARs.

Table 4: Key terms in adverse event monitoring

Term	Definition
Adverse event (AE)	Any untoward medical occurrence in a patient administered a study product and which does not necessarily have a causal relationship with this product
Adverse drug reaction	Any untoward and unintended response in a subject to an intervention that is related to any dose administered to that subject
Unexpected adverse reaction	An adverse reaction, the nature and severity of which are not consistent with information about the intervention in the investigator's brochure (or, for a product with marketing authorisation, in the summary of product characteristics for that product)
Serious adverse event (SAE), serious adverse drug reaction or unexpected serious adverse reaction	An adverse event, adverse drug reaction, or unexpected adverse reaction, that: <ul style="list-style-type: none">• results in death, or• is life-threatening, or• requires inpatient hospitalisation or results in prolongation of existing hospitalisation, or• results in persistent or significant disability or incapacity, or• consists of a congenital anomaly or birth defect, or• is a medically important event or reaction
Suspected unexpected serious adverse reaction (SUSAR)	Any unexpected serious adverse reaction that is suspected to be related to the intervention under study

Source: MHRA 2009

Terminating a study

- 13.54 In some circumstances, it may be appropriate to end an intervention study early.
- 13.55 For any study with a DMC, its monitoring plan should contain criteria and processes for early termination of the study. If the study is ended early, the process for doing so should follow the study's monitoring plan and the advice of the DMC. For any study without a DMC, the study's monitoring plan should comment on whether (and, if so, under what conditions) early termination of the study would be considered.
- 13.56 Therapeutic studies where participants are potentially receiving therapeutic benefit should not be terminated simply for reasons of commercial interest.

New information

- 13.57 When a researcher identifies new information that may impact on participants, they must handle it appropriately.
- 13.58 New information includes:
- changes to the research design
 - evidence of any new risks
 - unanticipated issues that have possible health or safety consequences for participants
 - new information that decisively shows one intervention is more beneficial than another
 - new research findings, including relevant non-trial findings
 - unanticipated problems involving lack of efficacy, recruitment issues, decisions to stop developing the item under study, or other matters seen as serious enough that they should be disclosed
 - closure of trials at other sites for reasons that may be relevant to the welfare or consent of participants in the ongoing research.

Maintaining safety of researchers

- 13.59 Researchers may sometimes be required to undertake activities in situations that put them at risk. For example, they may need to interview participants in their homes or undertake research in an unfamiliar cultural or social context. In these cases, researchers must make suitable arrangements for their own safety and document these in a safety protocol.
- 13.60 Given the variety of situations and activities that may be involved, no standard format exists for such a protocol. Usually, it includes arranging for colleagues or someone else to be aware of the researcher's travel plans or interviewing schedules, having suitable contact networks in the field and establishing a clear confirmation communication process before and after an appointment. In some cases, it may be appropriate for a colleague to accompany a researcher.
- 13.61 It is not usually acceptable for researchers to use their own homes to conduct research with participants.

- 13.62 Researchers travelling overseas need to be familiar with how best to conduct research within the culture and jurisdiction to which they are travelling.

Disclosing information

- 13.63 Researchers must protect individuals' privacy and confidentiality. The only exception is if they have an overriding ethical concern (for example, health or safety) justifying the release of such information, or if such release is required by law. If they must breach privacy or confidentiality, the researcher should first make a reasonable attempt to inform participants of such required infringements.
- 13.64 Certain areas of research (such as research involving children at risk of abuse or studies of criminal behaviour) are more likely to put researchers in positions where they may experience tension between the ethical duty of confidentiality and the competing duty to disclose particular information to third parties.
- 13.65 Researchers may have a duty to report certain issues arising when they are conducting research (eg, suspected abuse). They are expected to be aware of ethical codes or laws that may require them to disclose information they gain as researchers. Researchers are also expected to be aware of where to report these issues.
- 13.66 Researchers' conduct in such situations should be assessed on a case-by-case basis. They should decide on appropriate conduct in consultation with colleagues or any relevant professional body and/or with legal advice, taking into account the Health Information Privacy Code requirements.²⁶
- 13.67 Responsibilities to inform other health professionals of a participant's research involvement depend on the nature of the research. For some research, in the interests of the safety and wellbeing of the participant, researchers should, with the participant's consent, inform the health professional responsible for health care about the person's participation (usually at the time of enrolment in the research) and any possible health implications of this involvement. If a participant withholds consent, the researcher should consider whether it is ethical to enrol the participant in the study. For other research, informing other health professionals is desirable if the participant consents but it is not mandatory for safety.

Communicating and disseminating research results

- 13.68 Communicating study results is essential to realise the merit of the research. Researchers should communicate their study results in a time-sensitive and appropriate way so that benefits to the community are maximised and fairly distributed.
- 13.69 Researchers should not enter into contracts that limit, or apply unreasonable time restrictions to, the release of research results. Any proposed restrictions on publications must include an ethically acceptable justification. The onus to justify restrictions on disseminating or accessing data lies with the one seeking to make the restriction. Researchers have an ethical obligation to advocate for the release of information that is in the public interest, even when governmental or commercial sponsors retain the data.

²⁶ Privacy Commissioner. 2008. Health Information Privacy Code 1994: Incorporating amendments and including revised commentary.

Timing the release of results

- 13.70 If research results are not communicated within a reasonable time, their value may be diminished or lost and participants' contributions wasted. It can be difficult to determine the optimal time for releasing research results. Both premature release and unnecessary delay in release can be harmful to individuals and communities.
- 13.71 Where making the results available would immediately benefit participants, researchers are responsible for making them available to those affected as soon as practicable.

Releasing all results

- 13.72 Releasing all research results helps to prevent reporting bias. It is normally not appropriate to release incomplete research results (eg, release of early results, secondary end-point results or results from only some research sites), because incomplete results may be misleading. Negative results must also be effectively communicated as this adds to knowledge and may allow other researchers undertaking the same study to avoid wasting resources.

Interpreting and presenting study results

- 13.73 Researchers must strive to report study results accurately. They should anticipate and avoid any misinterpretation of those results.
- 13.74 Conflict may arise for researchers between doing no harm and openly disclosing research results. They may reduce any harm by presenting data in a way that protects the interests of those at risk and maintains research integrity.
- 13.75 Concerns about deficit thinking and victim blaming link closely to critiques about the way research analyses are framed. Deficit thinking is a catch-all term for various theories conjecturing that poor health outcomes are the fault of people's ethnicity, culture and/or socioeconomic status. For example, researchers should not look on the health disadvantage of Māori (such as consistently worse health outcomes) as inherent to Māori ethnicity (based on cultural stereotypes or beliefs). Similar considerations are raised for people with disabilities and their health outcomes. Rather than using deficit thinking, any analysis of the causes of these disparities should include a focus on their broad causes or drivers (including determinants of health and health system issues) and the consequences of systemic disadvantage. Ethical research should provide analysis and opportunity to advantage groups and therefore help to counteract negative stereotypes.
- 13.76 Avoiding deficit thinking is an important component of focusing research on improving outcomes for Māori. Including Māori researchers in the research team to inform the design and analysis of the research can help to address this risk, but it is the responsibility of the research team as a whole to ensure that the study is ethical. See [Research Involving Maori](#).

Returning results and incidental findings

- 13.77 Researchers should inform participants of any expected or possible implications of the study analysis. For example, the study results may impact on their ability to get insurance, employment or loans, and may also have social implications (eg, revealing previously

unknown paternity information). Researchers should also consider whether any study results have direct implications for the health of a participant's friends or family.

- 13.78 Incidental findings are observations of potential clinical significance that are unexpectedly discovered in research. Researchers have a duty or responsibility to inform participants of such findings, counsel them and ensure adequate follow-up is in place for them. Follow-up may involve referring the participants to a suitable health professional or specialist. Suitable counselling may be necessary for participants, depending on the information uncovered.
- 13.79 Before conducting research, researchers must develop and record a plan for how they will handle any individual test results or incidental findings. There is an ethical difference between findings participants may expect from analysis they consented to as part of their care or research participation, and findings that are unexpected or incidental. In developing their plan, researchers should consider whether to communicate to participants findings that are not clinically actionable.
- 13.80 Researchers should give participants the choice of opting out of receiving results of analyses that are not clinically significant or for which treatment is not available. It may be appropriate to offer this choice to participants at two points of the research: when they initially enrol in the research study and/or after the results are available. It is important to signal to participants when they enrol that they will be routinely asked to reaffirm their decision at the second point; this request will not be because of the nature of their results.

14 Health data

Introduction

- 14.1 Health data is used in most health and disability research studies. Its life cycle includes collection, use, analysis, publication, storage, curation and destruction (Figure 2).

Figure 2: The life cycle of research data²⁷



- 14.2 Researchers must justify data use, recognising the ethical tension between respect for individuals or groups (privacy, confidentiality, dignity, autonomy) and beneficence (generating new knowledge). Research involving health data should be motivated to distribute benefits and risk equitably (social equipoise).
- 14.3 Researchers must consider where the data has come from (eg, has the data been collected as part of the research study or does the research involve reusing data originally collected for other purposes?), the identifiability of the data, how the data will be used (eg, advanced data analytics and linking), whether those uses have been consented to by participants, how the data will be managed during the research and what will happen to it once the research has been completed (eg, will it be stored for later reuse or will it be destroyed?).
- 14.4 For research in the New Zealand context, some data is seen as taonga. The concept of taonga refers to something sacred, precious or significant. It can describe valued objects, significant resources or important entities. A taonga should be actively cared for in a

²⁷ Ingram. 2016. How and why you should manage your research data: a guide for researchers.

manner that preserves its integrity and value and that respects the tapu (sacred or protected status) that is part of the taonga.

- 14.5 The standards described in this chapter help researchers to consider the ethical issues related to all aspects of the life cycle of research data, including when it is stored in a databank and when it is linked with other sources and repositories of information.

Standards

- 14.6 Researchers must identify the possible benefits and risks of harm of data use, carefully balance them against each other and consider how to minimise and mitigate any harms of data use.
- 14.7 Participants must be informed of, and consent to, the collection and use of their data in research.
- 14.8 Researchers must only collect data necessary for the specified purposes of their research.
- 14.9 Researchers must collect data from participants in a manner that is lawful and fair and that does not intrude to an unreasonable extent on the personal affairs of the participant.
- 14.10 The people collecting data must be suitably trained, experienced and culturally knowledgeable. If they are new researchers, they must be supported by a suitable person.
- 14.11 Researchers must adequately protect participants' data both physically and electronically.
- 14.12 Researchers must give a higher level of protection to sensitive data (such as data associated with sexual health, mental health or illegal activities).
- 14.13 Researchers must protect participants' data and must only disclose it to people authorised by participants to access and/or use their data unless:
- disclosure of the data is required by law or
 - the researchers believe, on reasonable grounds, there is a serious and imminent threat to public health, public safety or the life or health of an individual and the disclosure has first been justified to an ethics committee (as an 'unauthorised disclosure').
- 14.14 Researchers must inform potential participants of any circumstances in which it may not be possible to protect their privacy and confidentiality and of any circumstances that may result in unauthorised disclosure of their data.
- 14.15 If unauthorised disclosure of participants' data has occurred, or is to occur, in accordance with standard 14.13 above researchers or data custodians must make reasonable attempts to notify affected participants as soon as practicable. The only exception is where the researchers believe on reasonable grounds that such notification would be contrary to the participants' interests or would be likely to prejudice the physical or mental health of the participants. In this case, the researchers must consider whether it would be appropriate to notify a representative of the participant.
- 14.16 Researchers must explain to participants, or their representatives, the steps that they are taking, or intending to take, in response to unauthorised disclosure. Researchers must take steps to minimise reasonably foreseeable harm before unauthorised disclosure and take reasonable steps to mitigate any harm caused by unauthorised disclosure.

- 14.17 Data must be stored and used in the least identifiable form possible. Researchers are responsible for identifying, assessing and minimising risks of harm related to re-identification.
- 14.18 Restrictions that participants place on the use of data must be recorded and respected.
- 14.19 Researchers must establish appropriate and robust data governance and data management during the life cycle of research data.
- 14.20 Researchers must recognise Māori rights and interests in relation to data and involve Māori in the governance of Māori data.
- 14.21 If a research study involves accessing data without consent, researchers must first obtain a [waiver](#) from an ethics committee by justifying the absence of consent in a way that recognises the requirements of these standards.
- 14.22 Identifiable data may be sent overseas for research if the person from whom the data was collected has consented to it. This consent should be based on the understanding that privacy protections in other countries may be different to those offered in New Zealand.
- 14.23 Researchers must obtain consent from a participant from whom data has been collected in a research study ('the original research study') to use that data for future research studies where:
- the purpose(s) of the future studies are [specified](#)
 - the purpose(s) of the future studies are an [extension](#) of, or closely related to, the purpose(s) of the original research study or are in the same general area of research as the original research study
 - it is not possible to identify the purpose(s) of the [future studies](#).

Standards – data linking

- 14.24 Researchers must seek consent from participants for research that involves data linking with identifiable data. The exception is where they have obtained a waiver from an ethics committee by justifying the absence of consent in a way that recognises the requirements of these standards.
- 14.25 Researchers must respect any existing consent that includes any conditions on data linking.
- 14.26 The amount of data linked must be the minimum required to answer the research question(s).
- 14.27 Data linking should be performed only by a restricted number of appropriately trained researchers.
- 14.28 Researchers should not hold linked data indefinitely.
- 14.29 Researchers should remove identifiers from the data once data linkage is complete.²⁸

²⁸ For further information see Scottish Informatics and Linkage Collaboration. Joined-up data for better decisions: Guiding principles for data linkage at <http://www.datalinkagescotland.co.uk/safeguarding>.

- 14.30 Suitable governance structures that ensure the data is being accessed and linked in an appropriate and responsible manner must be established.

Standards – databanks

- 14.31 Researchers must obtain participants' consent to submit their data to databanks, paying particular attention to the parameters of consented **future use(s)**. Researchers must also respect any conditions that participants have placed on the use of their data that has been stored in databanks.
- 14.32 In limited circumstances, researchers may use data stored in databanks **without consent** but they must first justify such use to an ethics committee.
- 14.33 Databanks must have a **governance** structure in place to protect the rights, dignity, autonomy, privacy and confidentiality of participants and their communities.
- 14.34 Relevant information on the governance of databanks should be made available to the public.

Commentary

Data identifiability

- 14.35 Accurately describing the identifiability of data is important in gaining informed consent and in determining the ethical risk of activities. Data may exist in three separate forms.
- **Identifiable data** is data from which it can reasonably be assumed that it is possible to identify a specific individual involved in the research. Identifying information includes, but is not limited to, names, initials, addresses, birth dates, phone numbers, email addresses, identifying numbers (eg, National Health Index number or Inland Revenue number), employment details and photos.
 - **Re-identifiable data** is data from which researchers have removed identifiable information and assigned a code, but it remains possible to re-identify a specific individual, for example, by using a code-key or linking different data sets.
 - **Non-identifiable data** is data that has never been labelled with individual identifiers or from which identifiers have been permanently removed, and for which there is no reasonable basis to believe that a specific individual can be identified. A subset of non-identifiable data is the data that can be linked with other data so it can be known that the two sources are about the same data participant, although the person's identity remains unknown.
- 14.36 These standards do not use the terms 'de-identified', 'anonymous' and 'anonymised' data because their meanings can be confusing.
- 14.37 Researchers should establish the extent to which data is re-identifiable. They are responsible for identifying, assessing and minimising risks related to re-identification. While measures to remove identifiers may help to protect privacy, re-identification may still be possible.
- 14.38 Data analysis involving data integration and linking may heighten risks of re-identification. This higher risk is particularly likely if the research relates to a population in a small

geographical area or is about individuals with unique characteristics, where a large number of variables relate to an individual.

- 14.39 Researchers should pay special attention to implementing measures to reduce any harms from re-identification. For example, they should keep identifiers for the minimum time necessary for the study, considering any need to identify participants (eg, for follow-up or to return clinical results). Special consideration needs to be given to whether data being retained for future use needs to be kept identifiable.
- 14.40 Whenever research using re-identifiable data reveals information that affects the health and wellbeing of participants, researchers must consider how to make that information [available to the participants](#), if participants have consented to receiving such information.

Benefits and harms from data use

- 14.41 Research data can generate benefits for individuals and the public now and in the future. If the data is not used, the public may be harmed or be denied benefits. At the same time, individuals and groups can be harmed by data use. Therefore, researchers must identify the possible benefits and risks of harm of data use, carefully balance them against each other and consider how to minimise and mitigate any harms of data use.
- 14.42 **Potential benefits from data use:** Data use may provide both individual benefits and public benefits. The nature, degree and likelihood of benefits resulting from research depend on the context and must be considered each time a new data use is proposed. Table 5 lists some of the main types of potential benefits.

Table 5: Some potential benefits from data use

Type of potential benefit
Clinically relevant information for an individual
Individual psychosocial benefit from contributing to research – eg, altruism
Sharing in scientific advancement and its benefits
Conducting rigorous and high-quality health research
Advancing collective values including: <ul style="list-style-type: none"> national research priorities health equality between different groups neglected diseases health conditions with high social cost
Reducing: <ul style="list-style-type: none"> risks of surveillance of specific populations individual or group discrimination stigmatisation predictive privacy risk (where privacy invasions occur through inference rather than direct collection of personal data)

- 14.43 Risk of possible harms from data use. Data use also presents risks of harm to individuals and groups. The nature, degree and likelihood of possible harms that research may cause depend on context and must be identified and considered each time a new data use is proposed. Table 6 lists some of the main types of possible harms.

Table 6: Some potential harms from data use

Type of possible harm	Indicator
Physical harms	Public attacks, spouse/partner abuse, domestic violence, delayed or inadequate treatment
Social harms	Discrimination, dignitary harm, community discrimination, isolation, inability to access care or exclusion from care
Economic harms	Loss of employment or revenue, loss of health care services, loss of insurance, increased insurance premiums, increased health care costs, limited career options, loss of life resources, forced relocation
Psychological or emotional harms	Distress, trauma, stigma
Legal harms	Arrest, prosecution, expulsion, loss of insurance
Privacy harm	Patients not accessing services because they believe their privacy is at risk
Interpretation harms	Inappropriate conclusions, apophenia (reporting patterns that are not there), implied causality rather than correlation, unrecognised data-quality issues, digital misrepresentation (eg, algorithmic bias)

- 14.44 Researchers must carefully consider how to minimise and address any harms that might result from data use.
- 14.45 Researchers must ensure significant decisions based on data involve human judgement and evaluation.
- 14.46 Researchers should pay attention to the context of data collection, which may impact on participants' privacy. For example, privacy may be at risk if the physical environment at the time of collection is a prison, rest home, hospital or place of employment.
- 14.47 Researchers should also pay attention to participants' preferences (eg, having whānau or family members present) and any cultural sensitivities. Whether a means of collection is unreasonably intrusive may depend on the context and sensitivity of the information, such as information relating to sexual life, ethnicity, HIV status, diseases or conditions carrying social stigma, mental health history, life expectancy or addiction. Researchers must establish a plan to manage any harms resulting from the data collection.

Data with special features

- 14.48 Research using health data requires special consideration when it:
- involves integrating or linking health data with data held by other entities (see specific standards for [linking data](#))
 - involves [ethnicity collection](#) (and, in particular, its data quality)
 - involves genetic data and interpretation of findings (which may cause stigmatisation)
 - is a novel use of data for the people or community it will affect
 - may have an impact on whānau, hapū, iwi or Māori communities
 - may have an impact on Pacific peoples or other communities
 - may have an impact on vulnerable groups such as children and young people

- may have a disproportionate impact on people from small communities or people identifying as disadvantaged
- has the potential to have a serious impact on people's lives
- involves sensitive information.

14.49 When research involves the special features identified above, researchers should carefully consider whether they should undertake robust, active and ongoing engagement with relevant communities and stakeholders to establish whether the proposed data use is acceptable. Any such [engagement](#) should be transparent and fair, done in good faith and be truthful, consistent with the concepts and practice of whakaponono and whakataukī.

Waiver of consent for use of data

14.50 For information on obtaining a waiver of consent for use of data, see the [section on research without consent](#).

Governance and management of data

14.51 Appropriate and robust policies, processes and procedures must be in place to manage data throughout its life cycle. This requires high-quality, transparent data governance and data management. Appropriate governance and management are especially important in cases where consent for data use has been waived, where there is data linking, or where unspecified future use is intended. For Māori data, key Māori Data Sovereignty principles include supporting Māori/iwi access to data and Māori/iwi governance of data.²⁹

14.52 While data governance and data management overlap in many ways, the key areas to consider are: 'who can take what actions with what information, when, under what circumstances and using what methods'.³⁰ The context of the study, including the kind of research and the level of risk of harm involved, will inform what data governance and data management frameworks are appropriate. These frameworks must be described in the research protocol or associated documents, and should include:

- the purpose(s) of the data collection, how data will be collected and by whom, including any training required for data collectors
- the proposed use(s) of participants' data, including any future use(s), linking and other analytics that may result in harm to the participants or others, such as their families, whānau, communities and groups
- details of the form (ie, identifiable, re-identifiable or non-identifiable) in which participants' data will be collected, accessed, used and stored at the different stages of the research and the measures proposed to remove identifying details
- who will access the participants' data
- plans for how consent will be sought for data collection and use and, if data collection and use are unconsented, plans for seeking a waiver of consent from an ethics committee
- how Māori rights and interests in relation to data will be recognised and how Māori will be involved in the governance of Māori data
- the length of time participants' data will be retained

²⁹ Te Mana Raraunga Māori Data Sovereignty Network. Nd. Our data, our sovereignty, our future.

³⁰ Data Governance Institute. 2017. The basic information.

- how the privacy and confidentiality of participants' data will be protected, including any circumstances in which it may not be possible to protect participants' privacy and confidentiality and any circumstances that may result in unauthorised disclosure of participants' data
- procedures for dealing with any breaches of privacy and confidentiality, including any unauthorised disclosure of participants' data, the measures that will be taken to notify affected participants and the measures that will be taken to mitigate any harm caused by unauthorised disclosure
- how researchers and others accessing and using participants' data will be held accountable for complying with requirements regarding the privacy and confidentiality of participants' data
- procedures for the return of results, including incidental findings
- plans for any commercial use of participants' data and proposals for benefit sharing, including intellectual property issues
- whether participants' data will be transferred to other countries and whether, in those countries, it will be subject to laws providing comparable safeguards to those available in New Zealand
- whether participants' data will be transferred to other institutions such as databanks and registries and who will access that data, how it will be used (eg, future use(s) and linking) and how privacy and confidentiality will be protected
- participants' rights to correct their data
- procedures for withdrawing participants' data
- procedures for destroying participants' data
- details of proposed approaches for any community engagement
- what measures will be adopted to ensure transparency across all aspects of the research data life cycle.

Data linking

14.53 Data linking is a technique for connecting pieces of information that are thought to relate to the same person, family, place or event. If these different pieces of information can be connected to a person in a way that does not breach their privacy or cause harm, linking them can create a rich resource for research to answer complex questions and improve outcomes for New Zealanders.³¹

14.54 When one or more data sets are linked, the risks of identification and adverse public reaction are likely to be greater, especially when the different data sources may have been designed and collected without the intention of using them together. This is because the data (which can be about individual people, households or organisations) may have been collected for different purposes, and combining it may create concerns that the extent and nature of the information produces a detailed picture of an individual, which they were unaware of when they supplied the data.³²

³¹ Adapted from the Government of Western Australia, Department of Health. What is data linkage? URL: <https://www.datalinkage-wa.org/what-is-data-linkage>

³² For further information on data linking please visit www.stats.govt.nz

- 14.55 For these reasons, privacy is a major consideration in any data linkage work. Researchers must weigh the potential benefits of the research against the risk that they will be able to identify individuals. See [benefits and harms section for health information chapter](#) and also general chapter on [benefits and harms](#)

Data linking without consent

- 14.56 Obtaining informed consent to link data must always be the default starting point. Where researchers propose to link data without specific consent for research, or where the proposed research is not consistent with the scope of the original consent, researchers may link data only if an ethics committee is satisfied that they meet the conditions for [waiver of consent](#).
- 14.57 Researchers must address the privacy risks of linking data by analysing the primary and secondary uses of the data, considering not just re-identification risks but also inference risks. That is, this analysis should take into account not only whether a person can be directly associated with a particular attribute, but also the extent to which attributes that may be revealed or inferred depend on an individual's data and the potential harm that may result. In addition, it takes into account the potential uses and analysis of the data, which in turn affect data governance and management.

Databanks

- 14.58 The term 'databanks' used in these standards encompasses a wide range of data types and methodologies from registries³³ to databanks.^{34 35 36 37}
- 14.59 Databanks provide a major resource for many public health and epidemiological research activities, ranging from disease prevention to resource allocation. By using them, researchers can significantly accelerate the improvement in the understanding of health, diseases and the effectiveness, efficiency, safety and quality of preventive, diagnostic and therapeutic interventions.
- 14.60 At the same time, databanks raise issues of dignity, autonomy, privacy, confidentiality and discrimination. These issues should be addressed by researchers in accordance with the following general principles.
- Research using databanks should contribute to benefiting society, in particular public health objectives.
 - Researchers have ethical and legal obligations to respect the dignity, autonomy, privacy and confidentiality of individuals when using data from databanks.

³³ Registries have organised systems that use observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition or exposure, and that serve one or more predetermined scientific, clinical or policy purposes. Such registries are variously described as patient registries, clinical registries, clinical data registries, disease registries and outcomes registries.

³⁴ Health databanks have organised systems for collecting, organising and storing health information. Databanks may pursue a specific, focused research agenda, collecting data for a limited time to answer a specific research question. Alternatively they may collect data over an indefinite time to answer a variety of existing and emerging research questions.

³⁵ CIOMS. 2016. Guideline 12.

³⁶ World Medical Association. 2016. Declaration of Taipei on ethical considerations regarding health databases and biobanks.

³⁷ National Health and Medical Research Council et al.2007, updated May 2015, Chapter 3.2.

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

Governance of databanks

- 14.62 Robust governance of databanks is important to maintain the public's trust in research that uses data from them. A databank must have a governance structure in place, which includes:
- the purpose of the databank
 - in broad terms, the types of research for which the databank may be used, along with any types of research that are not permitted or are permitted only after individuals have been re-consented
 - procedures for obtaining consent from participants for submitting data into the databank and using data stored in the databank, including the documentation of restrictions on [future use\(s\)](#) of participants' data, conditions on the identifiability of data, and other issues (eg, intellectual property rights) to ensure they are traceable and respected
 - criteria for when researchers may use participants' [data without consent](#) and the procedures that they must follow in this case
 - procedures for how participants may withdraw consent and any circumstances when it is not possible for participants to withdraw consent
 - criteria for determining when participants need to be re-contacted and the procedures that researchers are to follow
 - criteria for determining whether unsolicited findings should be disclosed and, if so, the procedures for disclosing them
 - criteria and procedures concerning who may access and use participants' data and under what circumstances
 - how researchers and others accessing and using participants' data will be held accountable for any unauthorised access to, or inappropriate or unauthorised use of, participants' data
 - measures for the physical and electronic protection of participants' data
 - procedures for quality control of data collection
 - procedures for research involving [data linking](#), including maintaining the confidentiality of the link between collected data and personal identifiers
 - mechanisms for keeping participants informed of research outcomes
 - how researchers will undertake participatory engagement with patient groups or the wider community and what other steps they will take to ensure transparency of the databank's operations
 - procedures for allowing participants to request corrections to mistakes and omissions of their data
 - arrangements for the storage, disposal and destruction of participants' data
 - the person or people who are responsible for the governance of the databank

- arrangements for dealing with participants' data if the databank has a change of ownership or closes
- arrangements for protecting the privacy, rights and welfare of participants whose data is stored in the databank, including using participants' data responsibly and respectfully and avoiding data use that [risks harm](#) to people to whom the data relates
- procedures for receiving and addressing enquiries and complaints.

Mandatory databanks

14.63 Government agencies may establish mandatory registries and databanks (eg, the New Zealand Cancer Registry), in which participants are obliged to provide data rather than volunteering or consenting to do so. Research using such registries and databanks may be mandated (eg, one of the purposes of the New Zealand Cancer Registry is to provide a basis for cancer survival studies and research programmes), which may not require ethical review or a waiver of consent. However, for research studies that use data from such databanks or registries and combine it with other data (eg, collected from participants via questionnaires), researchers must obtain participants' consent or seek a waiver of consent.

Legal requirements and other guidance

- 14.64 Researchers are responsible for complying with legal requirements, including those set out in the Code of Health and Disability Services Consumers' Rights, the Privacy Act 1993³⁸ and Health Information Privacy Code 1994.³⁹
- 14.65 The Privacy Act controls how agencies collect, use, disclose, store and give access to personal information. Almost every person or organisation that holds personal information is an 'agency'.
- 14.66 The Privacy Act gives the Privacy Commissioner the power to issue codes of practice that become part of the law. One of these is the Health Information Privacy Code. Codes may modify the operation of the Act for specific industries, agencies, activities or types of personal information.
- 14.67 The [Health Information Privacy Code](#) sets specific rules for agencies in the health sector. It covers health information collected, used, held and disclosed by health agencies and takes the place of the information privacy principles for the health sector.

³⁸ [Privacy Act 1993](#)

³⁹ [Health Information Privacy Code 1994](#).

15 Human tissue

Introduction

- 15.1 Human tissue⁴⁰ is commonly used in health research. Its use is increasing as the cost of new technologies decreases. This chapter begins by focusing on the ethical issues that relate to taking new samples from participants for a specified study as well as using existing samples for a specified study. It then addresses the special ethical issues associated with genetic research, while Chapter 17 focuses on stem cell research.
- 15.2 For the ethical considerations for using tissue in future unspecified research, see the [informed consent](#).
- 15.3 Research involving human tissue has special ethical considerations because of the:
- way that tissue is obtained – for example, it may be collected prospectively with consent from individuals or retrospectively from stored samples with or without consent
 - information that tissue may provide and the implications of that information for the individual donor, their blood relatives and their community
 - significance that may be attached to the tissue by individuals, donors and/or communities.
- 15.4 Some groups, especially Māori, hold beliefs about a sacred and/or shared value of human tissue and researchers should acknowledge and respect these beliefs. Specific issues to consider when working with Māori around tissue research and biobanking include:
- the tissue is a taonga – the tissue and any associated data are something of value that should be appropriately managed
 - protecting whakapapa is a key motivation, which involves protecting the connection between the tissue and the person from whom it originated, as well as the family and whānau
 - acknowledging the tākoha – tākoha is a form of gifting that recognises the tapu associated with a gift and indicates that conditions are to be applied to the taonga being gifted
 - the scope of [consultation](#) – given the range of views among Māori, researchers may need to consult beyond the family and whānau to include the wider community or iwi to gain support for the research project.⁴¹

⁴⁰ Tissue is a broad term that, in this chapter, refers to any biological material obtained from a living person or a body, including tissue, blood, urine, sputum, hair, nails and any derivative from these, including cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person. For legal purposes, human tissue is defined in section 7 of the Human Tissue Act 2008.

⁴¹ Hudson et al. 2016b. Te Mata Ira: Guidelines for genomic research with Māori.

- 15.5 Researchers must consider the ethical issues related to collecting and using human tissue alongside the issues related to the [information](#) derived from the tissue.
- 15.6 The use of stem cells in research is considered as a special case of tissue use. Chapter 17 presents separate, specific standards on this area of research.

New and existing tissue samples for a specified study

Standards

- 15.7 Researchers must treat samples of human tissue as Tākohā (donations or gifts). They must conduct research involving these samples with respect and transparency.
- 15.8 Researchers must consider the potential psychological, social and cultural significance of their use of tissue and plan to minimise all research harms.
- 15.9 The researcher must prepare and follow a tissue management plan. The plan must clearly describe the specific purpose of the tissue collection and how the researcher intends to process, store (including how long and where), distribute, use and dispose of the collected tissue.
- 15.10 Researchers should use existing tissue in an ethical manner and in accordance with the terms of the original gift or consent. Where possible, they should give preference to existing sources, if these fulfil the scientific goals of the research, rather than collecting new samples.
- 15.11 Researchers must not retain samples where they cannot justify continued storage. Equally they should not destroy samples where there is a clear rationale and ethical justification for continuing to store and use them.
- 15.12 Researchers must have a clear strategy in place for managing health-related findings (expected or incidental) from tissue analysis.
- 15.13 Those who collect, use and store the tissue must be suitably qualified or experienced (or supervised by those who are), and follow current best practice.
- 15.14 Access to tissue obtained for a study must be restricted to those who need it to undertake the study.
- 15.15 Researchers must get [informed consent](#) from the person from whom the tissue was or will be collected before they use it for research, unless a [waiver](#) of consent is approved by an ethics committee.
- 15.16 When research involves using clinical samples, researchers' use of tissue must not compromise the primary clinical reason for collecting the tissue.
- 15.17 Researchers must maintain participants' privacy and confidentiality throughout the period when the tissue is used and stored.

Commentary

- 15.18 Managing the ethical risks associated with the collection and use of human tissue in research includes:
- conducting the study according to a detailed and approved tissue management plan
 - obtaining a fully informed and voluntary consent for the collection and use from participants
 - managing privacy and confidentiality
 - returning results appropriately and [managing incidental findings](#)
 - giving special consideration to exporting or importing tissue.
- 15.19 The tissue management plan (contained in either the study protocol or laboratory manual) should specify:
- the methods of collection, volume of tissue to be collected and schedule of collection
 - measures taken to de-identify tissue samples and maintain privacy and confidentiality
 - method(s), location and duration of storage
 - planned analyses
 - access to tissue during the study
 - the fate of tissue after the study is completed, including details of any ongoing storage, potential distribution or access to other researchers, or return to donors
 - the method of disposal.
- 15.20 Researchers must communicate the above points in the tissue management plan to participants in plain, non-specialist language as part of obtaining a fully informed consent.
- 15.21 With advances in genetic analysis and data linking, and the prevalence of biobanks with identifiable tissue, human tissue samples should always be seen, in principle, as re-identifiable. The level of identifiability, or lack of identifiability, does not remove the ethical implications of using tissue in research.
- 15.22 It is desirable to remove unnecessary identifiers before storage and analysis to reduce the risk of confidentiality breaches.
- 15.23 Human tissue may be sent overseas for research if the person from whom the tissue was collected has consented to exporting it. It may also be sent overseas for analysis if that is necessary for a study conducted and ethically approved in New Zealand. Local iwi or site localities may have different views on exporting tissue and researchers should consult them early. To import tissue from another country for use in research in New Zealand, researchers should establish whether the tissue was obtained in a manner consistent with these standards. If they cannot establish this information, they should not use the tissue for research in New Zealand.
- 15.24 Before research begins, the study protocol or laboratory manual must contain a plan for how any individual test results or incidental findings will be handled. See [researcher conduct](#).

- 15.25 Researchers have a duty and responsibility to inform participants, counsel them and ensure adequate follow-up is in place after providing feedback on results or incidental findings. Follow-up may involve a referral to a suitable health professional or specialist. Suitable counselling may be necessary for participants, depending on the information uncovered. The study protocol should detail these plans.
- 15.26 Researchers should also consider whether any study results may have direct implications for the health of a participant's family, especially in the case of genetics research.

A special case of human tissue research: genetics

- 15.27 Genes and genetic information are being studied increasingly in clinical, epidemiological and social research, as well as in basic research.⁴² The guidelines in this section differentiate between research for which special precautions are necessary and research that is unlikely to be of concern to individual participants, their families or their communities. The standards are in addition to the standards on [human tissue](#).
- 15.28 Genetic research needs careful and specific ethical consideration because it may reveal information about predispositions to disease of both an individual and their family. Even though the disease may not develop in the individual, the information may have implications for access to employment and education, and to benefits or services, including financial services such as banking, insurance and superannuation. The information may also have important implications for blood relatives and family.
- 15.29 At a physical and spiritual level, whakapapa is embodied within the DNA of a person. Therefore the storage and use of human tissue for genetic or genomic research is a culturally informed activity. When individuals consent to participate in this type of research, the biological material and personal information contributed may be considered to be culturally significant by Māori and other groups.
- 15.30 Genetic research involves risks that the information may be misrepresented or misused in ways that lead to prejudice, stigma, disrespect, discrimination or other harms to participants, their families and communities. In designing, conducting and reporting genetic research, researchers must consider how to minimise such harms, and provide full information about the research risks to prospective participants.
- 15.31 For genetic research using stored data, see also [Chapter 16](#).

⁴² Genetic research may involve the study of:

- single or multiple genes, gene-to-gene interaction or gene–environment interaction
- acquired somatic variation
- inherited gene sequences, and their variants or their products
- gene expression, including environmental factors, pharmaceuticals and other therapeutic products
- the genes of individuals, families or populations
- epigenetics
- use of informatics and genetic information
- clinical phenotypes.
- genetic modification and gene editing.

Standards

- 15.32 Researchers must consider the potential psychological, social and cultural significance of their research and plan to minimise all research harms.
- 15.33 Researchers must prepare and follow a detailed plan for generating and using genetic material and information.
- 15.34 Researchers should inform clinicians or seek further advice if clinical action is possible in response to genetic information discovered, if participants consent to this.
- 15.35 Researchers must inform participants whether the research might generate information that the participant may be legally required to disclose to a third party (eg, for purposes of insurance, employment, finance or education).
- 15.36 Researchers must not use or release genetic material and data for purposes unrelated to the specific research without participants' consent, unless required by law.
- 15.37 If the research involves participants' family members, researchers must consider whether those family members are themselves participants and whether it is appropriate to seek their informed consent.

Commentary

- 15.38 Research results, genetic material and information collected for genetic research may be significant for research participants, their blood relatives and families, and may have complex and socially significant implications for communities. The research may create new options for life decisions, including those with potential to improve health. However, some individuals may prefer not to be given such information or even not to know of its existence. Family members who are not blood relatives, such as a partner or spouse, may have an interest because of concerns about the health of their children. Genetic research can also reveal information about previously unknown paternity or maternity. Genetic research has uses outside health, such as for tracing migration patterns and in studies of cultural relatedness.
- 15.39 Where research generates information of potential importance to the future health of participants and/or their blood relatives and family, researchers must prepare and follow a detailed protocol, which takes into account the clinical relevance of the research information, the types of genetic tests used in the research and the significance of those results for participants and others. The plan should also:
- enable participants to decide whether they wish to receive the information and who else may be given the information
 - give participants sufficient time to decide whether they wish to receive the information
 - set out a process for finding out whether other people want to receive information
 - detail the degree to which information would remain potentially identifiable
 - either provide for access to genetic and clinical advice and counselling about information of health significance, or clearly recommend to participants that they seek these services from professionals with appropriate training, qualifications and experience
 - detail the special provisions to protect the privacy and confidentiality of genetic information

- record any statutory or contractual duties that may require participants to disclose the results of genetic tests or analysis to third parties (eg, insurance companies, employers, financial and educational institutions), particularly where results provide information about health prospects
- detail any restrictions on the release of stored data or material, especially in studies of rare genetic disorders, for which it may be possible to identify certain individuals, families or members of the community even if information is given to others in non-identifiable form.

15.40 Where participants or relatives choose not to receive genetic information that is important for their health, researchers should advise them that they will be approached to confirm this decision when the results of the research are available, regardless of what the results show.

15.41 Before giving consent to genetic research, participants must be informed:

- about the degree to which confidentiality is possible, and of arrangements to keep genetic information private and confidential with regard to both family members and others, as well to future researchers who receive the material or information
- whether information from or about family members, in addition to that provided by participants, is required for the research
- whether, if a participant agrees for researchers to approach relatives, the participant has the opportunity to make initial contact
- whether the research may reveal information of potential importance to the participant's future health, or the future health of their children and other relatives.
- whether the research has the potential to detect previously unknown paternity or maternity, or non-blood relationship to siblings, and whether, how and to whom researchers will disclose this information
- that if the research discovers a family member may be at risk of a life-threatening or serious illness for which treatment is available or soon to be available, researchers may offer this information to the family member with the approval of a health and disability ethics committee even if the participant does not consent to this disclosure
- about the provisions for any extended or unspecified consent. [See duration of consent.](#)

15.42 Advice about the results of genetic research needs to include a clear explanation of the difference between research and clinical testing, and to clarify any need for clinical testing of research results. Where the potential relevance of genetic information to participants' health is not clear until after interim analysis of the research information, researchers should give participants:

- the option of being notified of the existence of that information
- the option of receiving the information and/or
- access to, or a recommendation to seek, advice or counselling about the possible implications of these decisions.

- 15.43 In research studying large numbers of genes simultaneously, participants may not be given the names of all the individual genes to be studied.
- 15.44 Genomic research involving identifiable hapū, iwi or Māori communities should ensure consultation with collective groups early on in the research planning phase.⁴³
- 15.45 Genomic research involving Pacific individuals or communities should comply with the Health Research Council's *Guidelines on Pacific Health Research*.⁴⁴

Gene editing

- 15.46 The technologies of gene editing for treating disease and for enhancing function are moving rapidly, and ahead of any consensus on how these technologies should be used. The technologies present complex ethical issues. Particularly complex issues relate to those genetic changes that would be passed on to future generations (such as CRISPR in human embryos), given that future people who will be affected cannot consent to the manipulation.
- 15.47 Where Māori embryos are considered, it is critical to follow culturally appropriate processes that ensure the key values of whakapapa, tika, manaakitanga and mana are upheld.
- 15.48 Currently, the Human Assisted Reproductive Technology Act 2004 substantially limits gene editing research in New Zealand.

⁴³ Hudson et al. 2016b. Te Mata Ira: Guidelines for genomic research with Māori.

⁴⁴ Health Research Council. 2014. *Guidelines on Pacific health research*.

16 Biobanks

Introduction

- 16.1 A biobank is a collection of human tissue samples stored for potential use in research beyond the life of a specific study. To be a biobank, a tissue collection must contain both:
- human biological materials with or without genetic information generated from their analysis
 - associated demographic and health information.
- 16.2 Some common features of biobanks are that they:
- are ongoing and open-ended, which often involves unspecified future research, allowing for the donation of tissue that is stored for definite or indefinite periods
 - need tissue and data to remain potentially re-identifiable, even if they are coded, because tissue and associated data may need to be linked to other sources of health information for studies in the future or to follow up information added over time
 - focus on the common good, with a greater concern for future public benefit than individual benefit for the participants themselves. Currently, many studies offer no direct or immediate benefit to individual donors.

Standards

- 16.3 To promote access to the benefits of research, researchers obtaining tissue samples for a biobank should collect and store tissue and make it accessible in such a way that this tissue can be used in future research.
- 16.4 Researchers should record any restrictions on the use of participants' tissue and make them known to other researchers who wish to access the biobank for their own studies.
- 16.5 Researchers and custodians of the biobank should observe any confidentiality agreement with the participant about stored tissue. Custodians should take every precaution to prevent the tissue from becoming available for uses to which participants did not consent.
- 16.6 Researchers' use of biobanks must comply with conditions that the providers of the tissue have specified.
- 16.7 Researchers and/or custodians must ensure that the biobank is used responsibly and respectfully and that the privacy of participants is safeguarded.
- 16.8 Researchers and/or custodians should consider denying or restricting access to some or all of the biobank for uses that could harm participants.
- 16.9 Researchers must justify any collection, use or retention of tissue beyond what they require for the study and they must gain separate consent for this activity.
- 16.10 If a biobank is closed, researchers should make plans for appropriate ways to transfer or dispose of the biological material and data.

Commentary

Informed consent

- 16.11 When seeking consent for storing tissue in a biobank, researchers should provide information on:
- the purpose of the biobank
 - risks and burdens associated with collecting, storing and using tissue
 - the nature of tissue they will collect
 - the form in which they will store the tissue (identifiable, re-identifiable or non-identifiable)
 - whether the researcher and/or custodian will seek: specific, extended or unspecified consent for future research; or approval from an ethics committee for use of identified or potentially identifiable tissue for research
 - the procedures for returning results, including incidental findings
 - governance arrangements, including the rules of access to the biobank, how they will protect privacy and confidentiality of participants, commercial use and benefit sharing, intellectual property issues and transfer of tissue or material to other institutions or countries.
- 16.12 Researchers must inform participants that if the tissue is made non-identifiable, then the participant may not be able to know what is done with their tissue and they will not have the option of withdrawing their consent.
- Extended or unspecified consent may sometimes need to include permission to enter tissue into a biobank. See the section on [modifying the informed consent process in Chapter 9](#).
 - When researchers seek unspecified consent, they should clearly explain its terms and wide-ranging implications to potential participants. When participants give such consent, researchers should clearly record its terms.
 - If a later research proposal relies on existing unspecified consent, it should describe the terms of that unspecified consent.
 - Research will sometimes need tissue additional to that covered by the original extended or unspecified consent. In this case, researchers must seek consent to access such additional tissue.

Limitations of consent

- 16.13 Consent does not protect all the interests of participants. In addition, it does not set aside the moral duty of care that researchers who can access the biobank owe to participants.
- 16.14 Researchers need to establish a coherent set of measures such as removing identifiers, the mechanisms for respecting participants' rights and interests (eg, consent procedures) and the forms of governance that guide the conduct of professionals in the public interest. They should work out these measures in relation to the underlying moral norms and values, and in relation to an agreed understanding of the hazards, benefits and uncertainties of tissue use in the context of particular tissue initiatives.

Governance

- 16.15 Researchers and/or custodians must provide additional safeguards in terms of appropriate governance and strict storage arrangements when they are keeping tissue for future unspecified use or for use in other studies.
- 16.16 Governance arrangements should cover:
- the purpose of the biobank
 - how the biobank will be used
 - the form in which the tissue will be stored (identifiable, re-identifiable or non-identifiable)
 - the rules of access to the biobank
 - how they will protect privacy and confidentiality of participants
 - the procedures for returning results, including incidental findings
 - commercial use and benefit sharing, intellectual property issues and transfer of tissue or material to other institutions or countries
 - measures to make all aspects of the biobank operation transparent
 - ways in which researchers will be accountable for complying with any requirements on access, use and privacy.
- 16.17 Researchers and/or custodians must involve a range of people with relevant interests when they are developing governance arrangements, as well as in the ongoing management of the biobank and periodic review of governance arrangements.
- 16.18 In developing governance arrangements, researchers and/or custodians should:
- identify potentially relevant values and interests
 - take special care to identify those people whose interests may be especially at risk and interests that arise from diverse values
 - identify the existing privacy norms in relation to contemplated uses
 - involve a range of people with relevant interests in the design of the biobank, including in establishing expectations about how it will be used.
- 16.19 When people with relevant interests participate in the design and governance of biobanks, researchers can identify relevant privacy norms and develop governance measures (eg, design of consent and authorisation measures) in relation to these norms.

Transparency

- 16.20 Participants have the right to request and receive information about their stored tissue and how it is being used.
- 16.21 Participants have the right to request that researchers correct mistakes or omissions.
- 16.22 Information on biobanks should be publicly available. This includes information on:
- who may have access to tissue and other information and for what purposes
 - tissue-sharing agreements and results of independent audits of compliance.

- 16.23 Researchers and/or custodians must keep an auditable record of all researchers who are given access to the biobank and the purposes of that access.
- 16.24 Researchers must report any privacy breach affecting a participant to that participant.

Public interests and privacy interests

- 16.25 The public has an interest in the responsible use of tissue to improve health and wellbeing of individuals, groups and all New Zealanders. Research using biobanks may lead to improvements in health care and service delivery, better targeting of services and greater understanding of risk factors.
- 16.26 Participants have an interest in controlling access to and disclosure of information relating to themselves, where that information is held in circumstances that they regard as confidential. They also have an interest in limiting the power of researchers or custodians to interfere with their individual privacy in the public interest.
- 16.27 Misuse of tissue can harm individuals, groups and communities. Such harm may involve loss of privacy, stigmatisation, discrimination and financial loss.
- 16.28 The broader public interest may come into conflict with individual privacy. Researchers and/or custodians should seek to avoid potential conflicts and violations rather than addressing them retrospectively.

Using identifiable tissue for accurate linkage

- 16.29 It may be permissible to use identifiable tissue to ensure the linkage is accurate, even if participants have not given consent for the use of the identifiable tissue. However, researchers must give assurances that the participant's identity is not further disclosed. When linkage is complete, researchers must remove identifiers from the tissue unless the participant has consented to its use in an identifiable form.
- 16.30 Where researchers seek access to biobanks that another organisation holds, it may be preferable for the biobank custodian to carry out the linkage and remove identifiers before disclosing the linked tissue.

Custodian (kaitiaki)

- 16.31 In most situations, the custodian of tissue will be the individual researcher or agency who collected the information, or an intermediary such as a tissue warehouse that manages tissue coming from a number of sources. In some cases, it may be necessary for a biobank to have an independent custodian. For example, when coded tissue is stored in a biobank, a custodian independent of both the tissue collectors and the researchers may be appointed to maintain the tissue in coded form while enabling individual participants to access their own identified results or tissue.

Transferring existing samples into a tissue bank when the donor is deceased

- 16.32 If the tissue is to be stored or used for a purpose other than research (eg, continued storage in a biobank), the conditions set out in section 31 of the Human Tissue Act 2008 must be met.

17 Research with stem cells

Introduction

- 17.1 Human stem cells are characterised by their capacity for self-renewal and their ability to differentiate into many types of cells of the body under the right conditions. The main goals of stem cell research are to identify the mechanisms that govern cell differentiation and to investigate the ability of human stem cells to form specific cell types that can be used for treating diseases and injuries. The two broad categories of stem cells are those derived from body tissues, known as somatic stem cells,⁴⁵ and those derived from embryos, known as embryonic stem cells.
- 17.2 Adding to the general considerations that apply to the ethics of research presented in these standards, and specifically to research with [human tissue](#), this chapter focuses specifically on both research with somatic stem cells and research that uses human embryos to create human embryonic stem cell lines. It sets out special considerations about collecting and using stem cells and stem cell lines, a stepped-level of informed consent (which distinguishes research and treatment), and health and disability ethics committee approval for establishing tissue banks for the storage of stem cells. It also distinguishes the future use of stem cells from protocol-specific research, especially the requirements for separate consent.
- 17.3 When considering research projects, researchers must assess their research goals within an ethical framework to ensure that proposed research with human embryonic stem cells proceeds in a transparent and responsible manner. The study proposal should discuss alternative methods (if available) and provide a rationale for using the requested human materials. This includes justification for use of human embryonic stem cells to be derived or used, for the proposed methodology, and for performing the experiments in a human rather than animal model system.
- 17.4 The following section in this chapter sets out the general standards for stem cell research, including the creation of both somatic and embryonic stem cells. The final section describes additional ethical considerations required for research with stem cells from human embryos.
- 17.5 The four main types of tissue that can be used to create stem cell lines are:
- adult adipose tissue
 - cord blood
 - bone marrow
 - induced pluripotent stem cell lines that could come from any somatic tissue.

⁴⁵ Somatic stem cells can be found in most body tissues in variable amounts, depending on the tissue type. Somatic stem cells retain the cellular programme of the tissues from which they originate but they can also be induced to form a limited range of other body tissues in-vitro. This means they are pluripotent and stem cells created from these are collectively known as induced pluripotent stem cells (iPS). Human embryonic stem cells are derived from the blastocyst at around five days of pre-implantation embryo development and have the potential to develop into all the tissues of the developing embryo. The means they are totipotent.

Stem cell research

Standards

- 17.6 All research concerning stem cells must comply with relevant legislation and guidelines.
- 17.7 All research involving the clinical application of stem cell-based interventions must be subject to prospective review, approval and ongoing monitoring by independent ethics committees.
- 17.8 Researchers creating a stem cell line must obtain informed consent for future use of tissue separately from informed consent for clinical treatment.
- 17.9 Research involving the development of new stem cell lines must be scientifically justified. It must also be conducted (and peer reviewed) by individuals with appropriate expertise.
- 17.10 For products derived from pluripotent stem cells, researchers must plan to minimise persistence of any remaining undifferentiated cells in the final product and demonstrate that these cells do not result in tumours in long-term animal studies, where appropriate.
- 17.11 Before any research begins, researchers must establish the specific risks and benefits associated with stem cell research. In addition, they must adopt practices that address long-term risks associated with the procedures.
- 17.12 Where applicable, a stem cell-based intervention must aim at being clinically competitive with or superior to existing therapies, or meet a unique therapeutic demand, or provide unique therapeutic outcomes.
- 17.13 Where applicable, researchers should recruit participants in clinical stem cell research from populations that can benefit from the results of this research.
- 17.14 Early-phase clinical trials involving stem cell-based interventions may enrol research participants who have run out of standard treatment options.
- 17.15 Researchers must not require participants to pay to participate in studies about emerging technologies such as stem cells.
- 17.16 Where stem cell lines are proven to have therapeutic benefit, researchers should distribute them to the appropriate research community to use.

Commentary

- 17.17 Research with stem cells may be associated with specific risks (such as cell contamination). Researchers must consider these risks in advance of their research and address them in any protocols.
- 17.18 Research with stem cells and lines is also subject to specific legislation and national guidelines. Although section 7 of the Human Tissue Act 2008 states that cell lines are not tissue, section 74 provides for regulations for their use in research. Legislation and guidelines relevant to stem cell research include:

- Human Tissue Act 2008 – relevant to collecting, storing and disposing of stem cells
- *He Tangata Kei Tua: Guidelines for Biobanking with Māori*⁴⁶
- the Ministry of Health’s guidelines on the use of stem cells (Ministry of Health 2006), which research that involves storing and disposing of human tissue stem cells must comply with
- Te Ara Tika: Guidelines for Māori Research Ethics.⁴⁷

17.19 As stem cell research uses identifiable human material or data (such as data contained in biobanks or similar repositories), researchers must seek informed consent for collecting, storing and/or reusing it. In some exceptional situations, consent for such research may be impossible or impracticable to obtain. In such situations, researchers may only conduct the research after a research ethics committee has considered and approved it.

17.20 Consent procedures for stem cell-based interventions should promote a full understanding of any possible benefits or therapeutic aspects of participating so that potential research participants do not overestimate or misunderstand them. Researchers should distinguish the protocol-specific intentions of the research from any future use of the material or data and obtain separate consent for each of these activities.

17.21 When a clinical trial involves human research participants with less advanced disease or when they anticipate using invasive delivery approaches for stem cells or cell-line products, researchers must follow stringent design and reporting standards.

Embryonic stem cell research

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

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

Standards

17.23 All research involving embryonic stem cells must comply with relevant legislation, namely the Human Assisted Reproductive Technology Act 2004, and the relevant guidelines of the Advisory Committee on Assisted Reproductive Technology.

⁴⁶ Hudson et al. 2016a. *He Tangata Kei Tua: Guidelines for bio banking with Māori*.

⁴⁷ Hudson et al. 2010. *Te Ara Tika: Guidelines for Māori research ethics*.

- 17.24 All research that involves pre-implantation stages of human development, human embryos or embryo-derived cells must be subject to ethical review, approval and ongoing monitoring by the Ethics Committee on Assisted Reproductive Technology. It must also address the uniquely sensitive elements of human embryonic stem cell research.⁴⁸
- 17.25 Researchers must not approach a woman about using fetal tissue in research until her decision about a termination of pregnancy has been clearly documented.
- 17.26 No compensation or reimbursement for the collection of gametes, embryos or fetal tissue for research may be made.
- 17.27 Researchers performing derivations of embryo-derived cell lines must have a detailed, documented plan for characterising, storing, disposing of, banking and distributing new lines.

Commentary

- 17.28 In addition to the above, research that uses or derives embryonic stem cell lines must be in accordance with the legislation and standards for stem cells described above, and follow the *Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research*.⁴⁹ The Human Assisted Reproductive Technology Act 2004 provides specific legislation relating to research on embryos up to 14 days. It prohibits:
- incorporating human totipotent or pluripotent cells into animal hosts to achieve chimerism
 - modifying the nuclear genome of human embryos for the purpose of human reproduction. This includes mitochondrial replacement therapy
 - culturing in-vitro any embryo-like cellular structure with human organismal potential, regardless of derivation method, beyond 14 days.
- 17.29 As with all stem cell research, studies involving embryonic cells can only be conducted by people with appropriate expertise and/or training. Relevant expertise for deriving new human embryo-derived cell lines includes previous experience with tissue culture techniques, embryo culture and stem cell derivation in animal systems, and competence in the culture and maintenance of human embryonic stem cells and cell lines.
- 17.30 The International Society for Stem Cell Research (ISSCR 2016) holds that scientific research on pre-implantation stage human embryos (especially research in human development, genetic and chromosomal disorders, reproduction and potential disease therapies) is ethically permissible when performed under rigorous scientific and ethical oversight.

⁴⁸ The Ethics Committee on Assisted Reproductive Technology cannot provide ethical review in some cases; for example, where the Advisory Committee for Assisted Reproductive Technology has not issued guidelines.

⁴⁹ Ministry of Health. 2006. Guidelines for using cells from established human embryonic stem cell lines for research.

18 Compensation for commercially sponsored intervention studies

Introduction

- 18.1 The Accident Compensation Act 2001 limits the circumstances in which a participant can receive treatment injury cover for personal injury suffered as a result of treatment given as part of a clinical trial.
- 18.2 In particular, participants are excluded from compensation if an approved ethics committee approved the trial and was satisfied that it was conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled ('commercially sponsored research').
- 18.3 For commercially sponsored research to be conducted ethically, researchers must satisfy an ethics committee that participants have access to compensation for injury to at least the equivalent of any Accident Compensation Corporation (ACC) compensation that would be available to them if they had been injured in research that was not commercially sponsored. Such compensation includes earnings-related compensation and compensation for surviving partners, children and dependants in the event of death ('alternative compensation'). This must include 'no-fault' compensation which is available to persons participating in non-commercial trials.
- 18.4 For commercially sponsored research, researchers and sponsors must comply with the following standards.

Standards

- 18.5 Alternative compensation must be available to participants for the whole period of the clinical trial from early-phase recruitment through to phase IV follow-up.
- 18.6 Participants' claims for alternative compensation must be resolved in a timely manner. If timely resolution is not achieved, claims must be referred to independent mediation.
- 18.7 As part of the informed consent process, researchers must clearly inform participants of:
- whether alternative compensation arrangements are legally enforceable
 - whether participants may need to engage their own lawyer to lodge an alternative compensation claim
 - whether the amount of the alternative compensation, if any, is at the sole discretion of the study sponsor and/ or their insurer
 - the jurisdiction in which any entitlement to, and amounts of, alternative compensation will be determined
 - details of mediation, appeal or review processes

- whether the alternative compensation is 'no-fault' compensation or whether fault on the part of the participants or researchers may impact on the availability and amount of the alternative compensation
 - whether any other material limitations apply to the availability of the alternative compensation, including the timing of payments
- 18.8 Study protocols, or associated documents, must provide details of the availability of the alternative compensation as referred to in these standards.
- 18.9 Researchers and/or sponsors must provide evidence to an ethics committee of appropriate levels of insurance to ensure any alternative compensation will be paid out to participants. In determining whether the level of insurance is appropriate, ethics committees will consider the type of research, including whether it involves vulnerable people or infants or children who, if injured, may require long-term, ongoing compensation.
- 18.10 Researchers must also provide evidence to an ethics committee of appropriate professional indemnity.
- 18.11 Researchers must give participants a study card that clearly states the participant is part of commercially sponsored research and is not covered by ACC for any injuries associated with the research. The study card must also provide the name of a contact person involved in the research who may be contacted in an emergency.

Bibliography

Accident Compensation Act (ACC) 2001.

Advisory Committee on Assisted Reproductive Technology. 2005. *Guidelines for Research on Gametes and Non-viable Embryos*. URL: https://acart.health.govt.nz/system/files/documents/publications/guidelines_for_research_on_gametes_and_nonviable_embryos.pdf (accessed 1 February 2018).

Anae M, Coxon E, Mara D, et al. 2001. *Pasifika Education Research Guidelines*. Wellington: Ministry of Education. URL: www.educationcounts.govt.nz/_data/assets/pdf_file/0010/7669/pacrsrch--guide.pdf (accessed 1 February 2018).

Andrej Z. 2014. Big data ethics. *Big Data & Society* 1(2). URL: <http://journals.sagepub.com/doi/abs/10.1177/2053951714559253#articleCitationDownloadContainer> (accessed 1 February 2018).

Beaton A, Smith B, Toki K, et al. 2015. Engaging Maori in biobanking and genetic research: Legal, ethical, and policy challenges. *The International Indigenous Policy Journal* 6(3).

Berg RM, Moller K, Rossel PJ. 2013. An ethical analysis of proxy and waiver of consent in critical care research. *Acta Anaesthesiologica Scandinavica* 57(4): 408–16. DOI: 10.1111/aas.12083 (accessed 1 February 2018).

Berger JT. 2011. Is best interests a relevant decision making standard for enrolling non-capacitated subjects into clinical research? *Journal of Medical Ethics* 37(1): 45–9. URL: <http://jme.bmj.com/content/37/1/45> (accessed 1 February 2018).

Brack M, Castillo T. 2015. *Data Sharing for Public Health: Key lessons from other sectors*. London: Chatham House. URL: www.chathamhouse.org/sites/files/chathamhouse/field/field_document/20150417DataSharingPublicHealthLessonsBrackCastillo.pdf (accessed 1 February 2018).

Calvey J. 2012. Including adults with intellectual disabilities who lack capacity to consent in research. *Nursing Ethics* 19(4): 558–67. DOI: 10.1177/0969733011426818 (accessed 1 February 2018).

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. 2014. *TCPS 2: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. Ottawa: Government of Canada. URL: www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf (accessed 11 February 2018).

Care of Children Act 2004.

Careerforce. 2015. *Pacific Values and Principles*. Christchurch: Careerforce. URL: <https://library.careerforce.org.nz/Learning%20Assessment%20Resources/LG25987-3.0.pdf> (accessed 2 February 2018).

CIOMS. 2016. *Guidelines for Health-related Research involving Humans*. Wellington: Council for International Organizations of Medical Sciences. URL: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> (accessed 1 February 2018).

Clinical Audit and Effectiveness Department. 2007. *The Difference between Audit & Research*. London: NHS Blood and Transplant.

- Commission on Human Rights. 1993. *The Mataatua Declaration on cultural and intellectual property rights of indigenous peoples. First international conference on the cultural and intellectual property rights of indigenous peoples*. URL: http://www.wipo.int/export/sites/www/tk/en/databases/creative_heritage/docs/mataatua.pdf (accessed 20 June 2018).
- Committee on Publication Ethics. 2017 *Ethical Guidelines for Peer Reviewers*. Committee on Publication Ethics. URL: http://publicationethics.org/files/Ethical_Guidelines_For_Peer_Reviewers_2.pdf (accessed 7 February 2018).
- COPE. 2017. *COPE Ethical Guidelines for Peer Reviews*. URL: https://publicationethics.org/resources/guidelines?f%5B0%5D=im_field_classifications%3A2779 (accessed 20 June 2018).
- Counties Manukau District Health Board. 2016. *Guideline: Ethical Guideline for Quality Improvement*. URL: <http://koawatea.co.nz/wp-content/uploads/2017/08/Ethical-Guidelines-for-Quality-Improvement-Gulideline.pdf> (accessed 1 February 2018).
- Crimes Act 1961.
- Cunningham C. 2000. A framework for addressing Māori knowledge in research, science and technology. *Pacific Health Dialog* 7: 62–9.
- Dickert NW, Brown J, Cairns CB, et al. 2016. Confronting ethical and regulatory challenges of emergency care research with conscious patients. *Annals of Emergency Medicine* 67(4): 538–45. DOI: 10.1016/j.annemergmed.2015.10.026 (accessed 1 February 2018).
- Douglass A. 2016. *Mental Capacity: Updating New Zealand's law and practice*. Dunedin: New Zealand Law Foundation.
- Equator Network. nd. *Enhancing the quality and transparency of health research* URL: <http://www.equator-network.org/> (accessed 20 June 2018).
- Ethics Research Involving Children. 2013. *ERIC*. URL: www.childethics.com (accessed 20 June 2018).
- Gillett G. 2014. Bioethical issues. *Journal of Law and Medicine* 21: 780–8.
- Government of Western Australia. 2018. Department of Health. What is data linkage? URL: <https://www.data-linkage-wa.org/what-is-data-linkage> (accessed 20 June 2018).
- Hazardous Substances and New Organisms Act 1996.
- Health and Disability Commissioner Act 1994.
- Health and Disability Commissioner. 1996. *Code of Health and Disability Services Consumers' Rights*. URL: <https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/> (accessed 20 June 2018).
- Health Disability Services (Safety) Act 2001.
- Health Practitioners Competence Assurance Act 2003.
- Health Research Council of New Zealand. nd. URL: <http://www.hrc.govt.nz/home> (accessed 20 June 2018).
- HRC. 2007. *Guidelines for Health Research with Children*. Wellington: Health Research Council of New Zealand. URL: <http://www.hrc.govt.nz/sites/default/files/HRC%20Guidelines%20for%20Health%20Research%20with%20Children.pdf> (accessed 1 February 2018).

- HRC. 2010. *Guidelines for Researchers on Health Research Involving Māori*. Wellington: Health Research Council of New Zealand. URL: <http://www.hrc.govt.nz/sites/default/files/Guidelines%20for%20Researchers%20on%20Health%20Research%20Involving%20M%C4%81ori%202010.pdf>
- HRC. 2014. *Guidelines on Pacific Health Research*. Wellington: Health Research Council of New Zealand.
- HRC. *Guidance Notes on Research Ethics*. Wellington: Health Research Council of New Zealand.
- Hudson M, Anderson T, Dewes TK, et al. 2017. 'He Matapihi ki te Mana Raraunga': conceptualising big data through a Māori lens. In H Whaanga, TK Keegan, M Apperley (eds), *He Whare Hangarau Māori: Language, culture and technology*.
- Hudson M, Beaton A, Milne M, et al. 2016a. *He Tangata Kei Tua: Guidelines for biobanking with Māori*. Hamilton: Te Mata Hautū Taketake – Māori & Indigenous Governance Centre, University of Waikato. URL: www.waikato.ac.nz/__data/assets/pdf_file/0019/321535/He-Tangata-Kei-Tua-Biobanking-Guidelines.pdf (accessed 1 February 2018).
- Hudson M, Beaton A, Milne M, et al. 2016b. *Te Mata Ira: Guidelines for genomic research with Māori*. Hamilton: Te Mata Hautū Taketake – Māori & Indigenous Governance Centre, University of Waikato. URL: www.waikato.ac.nz/__data/assets/pdf_file/0018/321534/Te-Mata-Ira-Genome-Research-Guidelines.pdf (accessed 1 February 2018).
- Hudson M, Beaton A, Reynolds P, et al. 2010. *Te Ara Tika: Guidelines for Māori research ethics*. Wellington: Health Research Council of New Zealand.
- Human Assisted Reproductive Technology Act 2004.
- Human Tissue Act 2008.
- Ingram C. 2016. *How and why you should manage your research data: a guide for researchers*. URL <https://www.jisc.ac.uk/guides/how-and-why-you-should-manage-your-research-data> (accessed 20 June 2018).
- ISSCR. 2016. *Guidelines for stem cell research and clinical translation*. Skokie, IL: International Society for Stem Cell Research. URL: www.isscr.org/docs/default-source/all-isscr-guidelines/guidelines-2016/isscr-guidelines-for-stem-cell-research-and-clinical-translation.pdf?sfvrsn=4 (accessed 10 February 2018).
- Jones RW. 2017. *Doctors in denial: the forgotten women in the 'Unfortunate Experiment'*. Dunedin: Otago University Press.
- Kim SY. 2016. Clinical trials without consent? *Perspectives in Biology and Medicine* 59(1): 132–46. DOI: 10.1353/pbm.2016.0023 (accessed 1 February 2018).
- Largent EA, Wendler D, Emanuel E, et al. 2010. Is emergency research without initial consent justified? The consent substitute model. *Archives of Internal Medicine* 170(8): 668–74. DOI: 10.1001/archinternmed.2010.80 (accessed 1 February 2018).
- Manning J. 2016. 'Without legal commitment': Compensation for research-related injury in commercially-sponsored clinical trials in New Zealand. In M Henaghan, J Wall (Eds), *Law, Ethics, and Medicine: Essays in honour of Peter Skegg* (pp 170–210). Wellington: Thomson Reuters.
- Manning J. 2016. Non-consensual clinical research in New Zealand: law reform urgently needed. *J Law Med* 23(3): 516–30. URL: <https://www.ncbi.nlm.nih.gov/pubmed/27323631> (accessed 1 February 2018).
- Manning J. 2009. *The Cartwright papers: essays on the cervical cancer inquiry of 1987–88*. Wellington: Bridget Williams Books.
- Medical Council of New Zealand. nd. Standards for doctors. URL: www.mcnz.org.nz/fitness-to-practise/standards-for-doctors (accessed 11 February 2018).

Medicines Act 1981.

Memorial Health. nd. *Determining the difference between clinical research and quality/performance improvement at Memorial University Medical Center*. Savannah: Memorial Health.

Mental Health (Compulsory Assessment and Treatment) Act 1992.

Miller FG, Emanuel EJ. 2008. Quality-improvement research and informed consent. *New England Journal of Medicine* 358(8): 765–7. DOI: 10.1056/NEJMp0800136 (accessed 1 February 2018).

Ministry for Pacific Peoples. 2017. *Kapasa: The Pacific Policy Analysis Tool*. Wellington: Ministry for Pacific Peoples. URL: www.mpp.govt.nz/library/policy-publications/kapasa (accessed 11 February 2018).

Ministry of Health. 2002. *Operational standard for ethics committees*. Wellington: Ministry of Health. URL: [www.moh.govt.nz/notebook/nbbooks.nsf/0/5ee9b561282cac41cc2578ae000c48d1/\\$FILE/OperationalStandard_final.pdf](http://www.moh.govt.nz/notebook/nbbooks.nsf/0/5ee9b561282cac41cc2578ae000c48d1/$FILE/OperationalStandard_final.pdf) (accessed 1 February 2018).

Ministry of Health. 2006. *Guidelines for using cells from established human embryonic stem cell lines for research*. Wellington: Ministry of Health. URL: [www.moh.govt.nz/notebook/nbbooks.nsf/0/7D723EE803F89C67CC2576D5006CBBCC/\\$file/guidelines-stem-cell-use.pdf](http://www.moh.govt.nz/notebook/nbbooks.nsf/0/7D723EE803F89C67CC2576D5006CBBCC/$file/guidelines-stem-cell-use.pdf) (accessed 11 February 2018).

Ministry of Health. 2007. *Guidelines for the use of human tissue for future unspecified research purposes*. Wellington: Ministry of Health. URL: <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> (accessed 11 February 2018).

Ministry of Health. 2008. *Operational standards for ethics committees*. Wellington: Ministry of Health. URL: <https://ethics.health.govt.nz/operating-procedures> (accessed 1 February 2018).

Ministry of Health. 2014. *'Ala Mo'ui: Pathways to Pacific health and wellbeing 2014–2018*. Wellington: Ministry of Health.

Ministry of Health. 2016. *New Zealand health strategy April 2016*. URL: <https://www.health.govt.nz/system/files/documents/publications/new-zealand-health-strategy-futuredirection-2016-apr16.pdf> (accessed 20 June 2018).

Ministry of Health. 2017. *HISO 10001:2017 Ethnicity data protocols*. URL: <https://www.health.govt.nz/publication/hiso-100012017-ethnicity-data-protocols> (accessed 20 June 2018).

Ministry of Health. 2017. *Therapeutic products regulatory regime*. Wellington: Ministry of Health. URL: www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime (accessed 11 February 2018).

Ministry of Pacific Island Affairs. 1998. *Pacific analysis framework with Pacific consultation guidelines*. Wellington: Ministry of Pacific Island Affairs. URL: [www.moh.govt.nz/notebook/nbbooks.nsf/0/0C0F5D6D16FA75FFCC256CE6007B97BC/\\$file/Pacific_analysis_framework.pdf](http://www.moh.govt.nz/notebook/nbbooks.nsf/0/0C0F5D6D16FA75FFCC256CE6007B97BC/$file/Pacific_analysis_framework.pdf) (accessed 2 February 2018).

National Ethics Advisory Committee – Kāhui Matatika o te Motu. 2012. *Āhukatanga ū ki te Tika me te Pono mō te Rangahau Māori: Māori research ethics: An overview*. Wellington: Ministry of Health.

National Ethics Advisory Committee. 2003. *Ethical review of observational research, audit and related activities: Discussion document*. URL: Wellington: National Health and Medical Research Council.

National Ethics Advisory Committee. 2012. *Ethical guidelines for observational studies: Observational research, audits and related activities. Revised edition*. Wellington: Ministry of Health. URL: <https://neac.health.govt.nz/system/files/documents/publications/ethical-guidelines-for-observational-studies-2012.pdf> (accessed 1 February 2018).

National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee. 2007 (updated May 2015). *National statement on ethical conduct in human research 2007 (updated May 2015)*. Canberra: Commonwealth of Australia.

New Zealand Bill of Rights Act 1990.

New Zealand Public Health and Disability Act 2000.

New Zealand Public Health and Disability Act 2000.

Nuffield Council on Bioethics. 2015. *The collection, linking and use of data in biomedical Research and Health Care: Ethical issues*. London: Nuffield Council on Bioethics. URL: http://nuffieldbioethics.org/wp-content/uploads/Biological_and_health_data_web.pdf (accessed 1 February 2018).

Pacific Research & Policy Centre. nd. *Pacific research guidelines and protocols*. Hamilton: Massey University. URL: www.massey.ac.nz/massey/fms/Colleges/College%20of%20Humanities%20and%20Social%20Sciences/pacific-research-and-policy-centre/192190%20PRPC%20Guidelines%202017%20v5.pdf?4D6D782E508E2E272815C5E3E1941390 (accessed 1 February 2018).

Privacy Act 1993.

Privacy Commissioner. 2008. Health Information Privacy Code 1994: Incorporating amendments and including revised commentary. Wellington: Office of the Privacy Commissioner. URL: www.privacy.org.nz/assets/Files/Codes-of-Practice-materials/HIPC-1994-2008-revised-edition.pdf (accessed 11 February 2018).

Protection of Personal and Property Rights Act 1988.

Pulotu-Endemann FE. 2001. *Fonofale Model of Health*. Auckland: Hauora. URL: www.hauora.co.nz/resources/FonofalemodelExplanation.pdf (accessed 1 February 2018).

Rid A, Wendler D. 2010. Risk–benefit assessment in medical research – critical review and open questions, *Law, Probability and Risk*, Volume 9, Issue 3–4, 1 September, pp 151–77, <https://doi.org/10.1093/lpr/mgq006> (accessed on 11 February 2018).

Sahan KM, Channon KM, Choudhury RP, et al. 2016. Refining the enrolment process in emergency medicine research. *European Journal of Cardiovascular Medicine* 4(1): 506–10. DOI: 10.5083/ejcm.20424884.147 (accessed 1 February 2018).

Scottish Informatics and Linkage Collaboration. 2018. *Joined-up data for better decisions: Guiding principles for data linkage*. URL: <http://www.datalinkagescotland.co.uk/safeguarding> (accessed 20 June 2018).

Smith B, Tolich M. 2014. A cultural turn: The trivialisation of indigenous research ethics in New Zealand post-2012 health and disability ethics committees. *MAI Journal* 3(2): 255–67.

Spirit Group. 2013. *Spirit Statement*. URL: <http://www.spirit-statement.org/> (accessed 20 June 2018).

Stats New Zealand. 2017. URL www.stats.govt.nz (accessed 20 June 2018).

Sullivan MJ. 2009. Philosophy, Ethics, and the Disability Community. *The Handbook of Social Research Ethics*. Mertens, DM, Ginsberg-Sage (eds). DOI: <http://dx.doi.org/10.4135/9781483348971.n5>.

Te Mana Raraunga Māori Data Sovereignty Network. Nd. *Our data, our sovereignty, our future*. URL: www.temanararaunga.maori.nz (accessed 20 June 2018).

The Data Governance Institute. 2017. *The basic information*. URL: www.datagovernance.com/the-basic-information (accessed 20 June 2018).

Tobias M, Yeh L. 2009. How much does health care contribute to health gain and to health inequality? Trends in amenable mortality in New Zealand 1981–2004. *Australian and New Zealand Journal of Public Health* 33: 70–8. doi: 10.1111/j.1753-6405.2009.00342.x

Treaty of Waitangi Act 1975.

United Nations. 2007. United Nations Declaration on the Rights of Indigenous People. URL: <https://www.un.org/development/desa/indigenouspeoples/declaration-on-the-rights-of-indigenous-peoples.html> (accessed 20 June 2018).

United Nations Climate Change. 2018. *Talanoa Dialogue Platform*. URL: <https://unfccc.int/process/the-paris-agreement/2018-talanoa-dialogue-platform> (accessed 20 June 2018).

United Nations. 2006. *Convention of the Rights of Persons With Disabilities – Article 12*. URL: <https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/article-12-equal-recognition-before-the-law.html> (accessed 20 June 2018).

University of Otago. 2011. *Pacific Research Protocols*. Dunedin: University of Otago. URL: www.otago.ac.nz/research/otago085503.pdf (accessed 1 February 2018).

US Department of Health and Human Services Health Resources and Service Administration. 2011. *Quality Improvement*. URL: www.hrsa.gov/sites/default/files/quality/toolbox/508pdfs/qualityimprovement.pdf (accessed 1 February 2018).

Wendler D, Dickert NW, Silbergleit R, et al. 2017. Targeted consent for research on standard of care interventions in the emergency setting. *Critical Care Medicine* 45(1): e105-e110. DOI: 10.1097/CCM.0000000000002023 (accessed 1 February 2018).

Workman TA. 2013. Engaging patients in information sharing and data collection: the role of patient-powered registries and research networks. Community Forum White Papers. Rockville, MD: Agency for Healthcare Research and Quality.

World Medical Association. 2006. *WMA declaration of Taipei on ethical considerations regarding health databases and biobanks*. URL: <https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/> (accessed 20 June 2018).

World Medical Association. 2017. *WMA Declaration of Helsinki – ethical principles for medical research involving human subjects*. URL: www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects (accessed 1 February 2018).

How to have your say

The consultation will be open until 5pm, 20 September 2018.

To take part in the consultation, please complete the online consultation at <https://consult.health.govt.nz/neac/national-ethics-standards> (Citizen Space).

If you cannot complete the consultation online please print out this document, write your submission and send it to:

NEAC Secretariat
Ministry of Health
PO Box 5013
Wellington 6011

There will also be public face to face meetings during the consultation. Please see <https://neac.health.govt.nz/> for meeting dates and venues.

If you have any questions, please contact us by email at neac@moh.govt.nz.

NEAC is seeking feedback on the following:

- **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 is aware of the complexity of ethical issues surrounding health and disability research. Therefore the consultation document provides the opportunity to provide detailed feedback on specific areas of the draft standards. As a submitter you are welcome to provide as much or little feedback as you want.

This consultation standards is sectioned into two parts.

The first is about the Standards as a whole, and asks questions about the new structure, the scope of the standards and whether they are complete. These are required to be completed.

The second part of the consultation is asks questions about each individual section (Ethical principles onwards).

You do not have to provide feedback on every section / chapter.

Each section has a set of standard questions, as well as some particular questions relevant to that section.

Submitter details

It will be helpful for NEAC, when assessing submissions, if submitters provide information about themselves. However, providing this information is not required for a submission to be considered, and you can choose to withhold this information if you wish.

This submission was completed by: *(name)* _____

Address: *(street/box number)* _____
(town/city and postcode) _____

Email: _____

Organisation (if applicable): _____

Position (if applicable): _____

Are you making this submission *(tick one box only)*:

- as an individual?
- on behalf of a group or organisation?

Privacy

We may publish all submissions, or a summary of submissions on the Ministry of Health's website. If you are submitting as an individual, we will automatically remove your personal details and any identifiable information.

If you do not want your submission published on the Ministry's website, please tick this box:

- Do not publish this submission.

Your submission will be subject to requests made under the Official Information Act. If you want your personal details removed from your submission, please tick this box:

- Remove my personal details from responses to Official Information Act requests.

If your submission contains commercially sensitive information, please tick this box:

- This submission contains commercially sensitive information.

Consultation questions process

Although the submission form includes blank spaces for answering the questions, these do not set a limit for the length of your responses and you should take as much space as you need to answer or comment. Feel free to enlarge the boxes or attach additional pages.

You may skip questions from Ethical Principles onwards by leaving them blank or clearly indicating that you are not commenting on that question.

Part one: general feedback

Please choose the number that best represents your response to each of the statements that follow.

Fit for purpose

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline your reasons.

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline your reasons.

3 The standards balance protecting individuals with the realities of conducting research.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline your reasons.

4 The standards support researchers to navigate ethical challenges in health research.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline your reasons.

4.a Overall do the guidelines?

	5 Strongly disagree	4 Disagree	3 Neutral	2 Agree	1 Strongly Agree
safeguard the rights and interests of participants in research					
promote high-quality ethical research for social, cultural and economic wellbeing					
reflect the principles of the Treaty of Waitangi					
foster awareness of ethical principles and practices among health care providers, researchers and the wider community					
help researchers think through and take responsibility for the ethical issues in their studies					
help researchers give due consideration to local and national community views and perspectives					
protect and reassure the community.					

Coverage of ethical guidance

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please describe the ethical challenges that are missing.

Merging the observational and interventional guidelines

- 6 The standards are applicable to both observational and interventional research.

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline your reasons.

Scope of the standards and non-research activities

In January and February 2015, the National Ethics Advisory Committee (NEAC) sought feedback on the cross-sectoral ethics arrangements for health and disability research, issues with these arrangements and ideas for enhancing them. One of the questions related to audit and related activities. A theme was the difficulty in determining what an activity was, research or not research, and subsequently the appropriate level of oversight.

The NEAC standards are written for a research audience, as well as those who support research including ethics committees and research offices. The standards are likely to be used to determine oversight of activities. The 2012 set of ethical guidelines contained some guidance on the distinction between research and non-research activities. This distinction is used to help determine ethical oversight, and in some cases whether informed consent is required (for example with audits, which routinely do not require consent). Most submitters did not think that the current classification acts as a barrier to audit and related activity. But many noted that the unclear distinction between observational research and audit could result in:

- unnecessary ethical review of audits and related activities
- weakening of research methodology to avoid HDEC review
- failure to publish important generalisable findings.

Definitions have been included in the draft standards, and some have been tightened, however how to determine what an activity is has not been included.

It is difficult to provide a clear cut distinction for the following reasons:

- The intent or aim (and justification) of both research and non-research activities relating to health and disability is often to improve patient outcomes.
- In both kinds of activities, the patients who benefit may be different to those who are involved in the activities.
- Creating knowledge is fundamental to research but is also clearly the aim of audit. Although some might claim broadly that research aims to create generalisable knowledge:
 - some kinds of health and disability research (eg, qualitative research) do not have this aim
 - some non-research activities clearly produce generalisable knowledge. For example, the audit of a particular department might well alert others to relationships between outcomes and practice in their own location.
- Some methods used in research are often also used in non-research activities. For example, many forms of research collect and analyse patient data but so do those who are auditing a clinical department.
- Both research and non-research activities can carry risk of harm – but some research may not go beyond minimal risk.

The Standards contain more information on determining risk and benefit of activities which may assist in determining appropriate level of oversight, opposed to oversight based on classification.

7 Is the scope of the document clear?

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline your reasons or suggested improvements.

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

Yes

No

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

Part two: feedback on sections

Ethical principles

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

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

- Yes
 No

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

Research involving Māori

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

Research involving Pacific peoples

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

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

- Yes
 No

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

Categories of participants

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

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

- Yes
 No

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

Informed consent

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

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

- Yes
 No

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

Research with participants who are unable to consent

NEAC's role is to determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services. NEAC must also ensure that any advice and guidelines comply with the laws of New Zealand. This requirement created a tension between providing ethical guidance that may be in conflict with New Zealand law. NEAC notes that the law on research with participants who are unable to consent restricts when research can be carried out in this population.

Once researchers have demonstrated that the participation of individuals who are unable to consent are necessary to answer the research question, Researchers must balance risks of harm with benefits.

Although in some cases it may be ethically justifiable to use different calculations of benefit and harm depending on the level of risk to which the participant is exposed, as well as whether the participants in the study have potential prospective benefit derived from their involvement, New Zealand law requires participation in all cases of health research without consent to be in the individual participants' best interest.

Therefore NEAC was unable to set alternative levels of risk and benefit as that guidance / those standards would not be able to be legally met.

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

Please outline your reasons.

Deception

The standards must apply to all cases of health research. In some fields of research, for example psychological research, deception may be used for scientific validity. Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective non-deceptive alternative procedures are not feasible. NEAC has not considered

deception as inherently unethical, but it should only be used as a last resort, not as a first resort, and certainly not a norm in health research.

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

Please provide feedback.

Research benefits and harms

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

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

- Yes
- No

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

Research development and design

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

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

- Yes
- No

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

Types of studies

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

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

- Yes
 No

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

Research conduct

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

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

- Yes
 No

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

Charging participants

- 36 NEAC acknowledge that charging participants is an ethical dilemma that has not been addressed in earlier guidelines. The current guidance places a high barrier to charging participants. Are the above standards a high enough barrier to very seldom allow charging for participation, and only permit it when it would facilitate important research?

Please outline your reasons.

Health information

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

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

- Yes
- No

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

Big data and new ways of using data

Use of data for research is becoming increasingly complex, involving linking across different agencies and use of algorithms or artificial intelligence. The ethical standards provide guidance when using data in order to increase public benefit while respecting people.

40 Do the standards present a reasonable balance between facilitating use of data while respecting rights to privacy and respect of people?

Please provide feedback.

Databanks

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

--

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

- Yes
- No

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

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Human tissue

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

--

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

--

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

- Yes
- No

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

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Biobanks

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

--

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

--

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

- Yes
- No

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

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Research with stem cells

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

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

- Yes
- No

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

Compensation for commercially sponsored intervention studies

General questions

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

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

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

5	4	3	2	1
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Please outline any missing ethical issues or principles.

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

- Yes
- No

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