



National Ethics Advisory Committee

Kāhui Mataatika o te Motu

National Ethical Standards

**Health and Disability Research
and Quality Improvement**

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Foreword

by the Associate Minister of Health

New Zealand is committed to a world leading health research system. The *New Zealand Health Research Strategy 2017-2027* has set the direction for prioritising and investing in health and disability research to address equity issues and improve health outcomes to the benefit of all New Zealanders.

The first step is to ensure the health research system in which we innovate and learn is one grounded in ethics. The National Ethical Standards for Health and Disability Research provide the foundation on which communities and researchers can design and conduct high quality ethical research.

The National Ethical Standards update and expand on previous guidelines issued by the National Ethics Advisory Committee in 2012 and bring together the Ethical Guidelines for Observational Studies and the Ethical Guidelines for Intervention Studies into one document. Having all research ethics guidance in one document makes for easier access for all users.

The Standards are consistent with the strategic priorities of the New Zealand Health Research Strategy which sets out four guiding principles for the health system: research excellence; transparency; partnership with Māori and collaboration for impact.

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 from harm from research, protects the privacy of individuals, and respects the mana (status) of families and whānau.

The National Ethical Standards will help all researchers including new researchers and in-training researchers, foster awareness of ethical principles and enhance more rapid translation of research into clinical practice and health services delivery.

The National Ethical Standards for Health and Disability Research will ensure researchers can safeguard the rights and interests of participants in research, while achieving the goal of increasing well-being and contributing to equitable health outcomes for all New Zealanders.

Hon Jenny Salesa

Associate Minister of Health 2019



Foreword

by NEAC Chairperson

The National Ethics Advisory Committee (NEAC) is an independent advisor to the Minister of Health. NEAC'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.

A central focus of NEAC's role is to set the national standards for the ethical conduct of research involving human participants that apply to all health and disability research in New Zealand. In 2015 NEAC committed to review the Ethical Guidelines for Intervention Studies and Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities. Though these two documents were updated in 2012, the present iteration represents the first major reconsideration of the Standards since their inception.

The revised Standards merge the two sets of guidelines into one cohesive document, which also aims to cover gaps and new ethical issues that have become apparent since the 2012 Guidelines.

Human participant research is the recognised basis for improved understanding of health and disability outcomes. Hence, there is a strong ethical imperative to research, and a necessity to involve human participants in research.

The Standards form part of the strengthened regulatory framework to continue to support a productive and safe clinical trials research environment in New Zealand. They aim to provide protections for those who are asked to participate in research, and those who do participate, ensuring that their rights and well-being are central.

They also aim to reassure the New Zealand public, as potential participants in and potential beneficiaries or sponsors of research that the research enterprise is trustworthy, and that it is worth their participation, confidence, investment and support.

Public trust in the ethical integrity of the research enterprise is increasingly important. The continual development of new research methods requires oversight of their ethical implications, as is the case with research using large data sets. Ethical oversight and governance of research is an important contributor to this trust.

From the outset of this revision, it has been NEAC's intention to integrate Māori values into the fabric of the guidelines. The values used for this purpose are those originally developed for Te Ara Tika - Guidelines for Māori Research Ethics. Internationally recognised values of bioethics, which are found in similar sets of health and disability research guidelines in many parts of the world, sit alongside the Māori values.

Significant efforts have also been made to reflect the aspirations and values of the disability community, recognising the important distinction between ill-health and disability, and trying to reflect consequent ethical distinctions.

For the first time, the Standards will be available principally on line. This will we trust, make their use easier and enable them to be a living document in response to innovations in research methods and models.

NEAC commends the work of the Guidelines Working Party which produced the bulk of the Standards, and we thank all those individuals and groups who have engaged in our consultation processes, which made a significant contribution to the guidelines as they now stand. We believe they will be of national and international significance.

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke extending to the right.

Dr Neil Pickering

Chair, National Ethics Advisory Committee

Introduction to the Standards

The National Ethics Advisory Committee – Kāhui Matatika o te Motu (NEAC) issues the National Ethical Standards for Health and Disability Research and Quality Improvement (the Standards) in line with its statutory functions. In particular, the Standards fulfil NEAC's statutory obligation to 'determine nationally consistent ethical standards across the health sector' ([New Zealand Public Health and Disability Act 2000](#)).

These standards set out the ethical requirements that:

- researchers¹ must meet or exceed when undertaking health and disability research **and**
- health service providers and disability service providers² must meet or exceed when conducting quality improvement activities.

The Standards apply whether or not research or quality improvement activities require review by an ethics committee.

The key objectives of the Standards are to:

- safeguard the rights and interests of participants in research and quality improvement
- 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 and improvement practitioners think through and take responsibility for the ethical issues in their studies
- help researchers and improvement practitioners give due consideration to local and national community views and perspectives
- support the consistent ethical review of health and disability research and quality improvement
- protect and reassure the community.

¹ The Standards primarily use the term 'Researcher' throughout when referring to corresponding responsibilities, however it should be understood that these Standards use the term Researcher broadly, intending to address all those responsible for the conduct of health and disability research, quality improvement activities, data and tissue governance, and any other activity described in the Standards.

² Health service providers include health service workers, nurses, clinicians and any person involved in quality improvement.

The Standards are primarily aimed at researchers, because researchers have the main responsibility for conducting ethical research. Increasingly, health research and quality improvement involve responsibilities that are broader, extending to institutions and organisations. The Standards primarily use the term 'Researcher' throughout when referring to corresponding responsibilities, however these Standards use the term Researcher broadly, intending to address all those responsible for the conduct of health and disability research, quality improvement activities, data and tissue governance, and any other activity described in the Standards.

They will also be of interest to others with a role or interest in health and disability research, including review bodies, industry, custodians, clinical managers or individuals with institutional oversight of research, government departments and research participants (individuals and communities).

The Standards have been informed by specific documents and statements in Aotearoa New Zealand, and by international ethical guidelines (see '[Bibliography](#)'). They do not provide detailed guidance on every possible research situation. Where other guidelines and codes of practice are consistent with the Standards, we recommend that researchers refer to them for additional ethical guidance on how to meet the Standards. The Standards assume that researchers are familiar with international and domestic ethical guidance materials relevant to their area of research (see '[Other ethical guidance documents](#)' for links to some of these resources).

Research in the New Zealand context

The Treaty of Waitangi and the standards

Māori, as the indigenous people of New Zealand, and the Crown are signatories to Te Tiriti o Waitangi/The Treaty of Waitangi, which sets the foundation for the enduring relationship between Māori and the Crown as equal partners. The Government – representing the Crown – continues to respond to its obligations to honour the Treaty relationship. Māori seek to overcome the particular challenges they still face in the postcolonial context, and participate equally in the partnership defined by the Treaty’.

Three principles derived from the Treaty of Waitangi, rangatiratanga (partnership), whai wahi (participation) and kaitiakitanga (protection) should inform the interface between Māori and research³ (Royal Commission on Social Policy 1988):

- rangatiratanga: researchers, iwi, hapū, whānau and Māori communities working together to ensure Māori individual and collective rights are respected and protected
- whai wahi: involving Māori in the design, governance, management, implementation and analysis of research, especially research involving Māori
- kaitiakitanga: actively protecting Māori individual and collective rights, Māori data, Māori culture, cultural concepts, values, norms, practices and language in the research process.

The Treaty partnership provides an opportunity to design together an advanced national health and disability research ethics platform that encompasses two world ethical views: that of western ethics and that of tikanga Māori (Māori ethics).

These Standards extend the work of previous committees, in that they now incorporate tikanga Māori, and make more logical links between Māori research theory and practice. In so doing, they are consistent with the strategic priorities of the New Zealand Health Research Strategy (Ministry of Business, Innovation and Employment and

³ See <https://www.waitangitribunal.govt.nz/treaty-of-waitangi/meaning-of-the-treaty/>

Ministry of Health 2017). That strategy contains four guiding principles: research excellence, transparency, partnership with Māori and collaboration for impact.

These Standards also recognise He Korowai Oranga – the Māori Health Strategy (Ministry of Health 2014b), 'Ala Mo'ui: Pathways to Pacific Health and Wellbeing (Ministry of Health 2014a) and the principles of Vision Mātauranga⁴ to:

- set a priority for Māori health research: to seize opportunities for addressing 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; for example, with respect to data sovereignty
- 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.

Research excellence entails 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 and acceptable to communities.

Strategic focus

New Zealand is a culturally diverse country. Researchers must take into account cultural viewpoints to ensure their research reflects the context and perspective of the society in which it occurs, to respect participants and to ensure that evidence generated from health research is effectively implemented.

A world-leading health and disability research and innovation system builds on existing knowledge, generates new knowledge and responds to the needs of the populations it serves. Consumers have a right to high-quality health care. These Standards recognise the vital importance and value of health and disability research, health services research and quality improvement activities to inform clinical management and public health, social and disability policy.

⁴ Information on Vision Mātauranga is available on the Ministry of Business, Innovation and Employment website (<https://www.mbie.govt.nz/science-and-technology/science-and-innovation/agencies-policies-and-budget-initiatives/vision-matauranga-policy/>).

To meet the needs of New Zealand populations in the future, our health and disability research will need to address the pressures that we anticipate will fall on our health system. The New Zealand Health Research Strategy (Ministry of Business, Innovation and Employment and Ministry of Health 2017) and He Korowai Oranga – the Māori Health Strategy (Ministry of Health 2014b) provide health and disability research in New Zealand with clear direction for doing so.

Addressing the health and disability needs of New Zealanders often involves discussion of inequity and inequality. Previously, these terms were used interchangeably; now, there is a clear distinction between the two. The World Health Organization (WHO) defines 'health inequalities' as differences in health status, or in the distribution of health determinants between different population groups. For example, differences in mobility between elderly people and younger populations, or differences in mortality rates between people from different social classes (WHO 2019b). It defines equity as 'the absence of avoidable, unfair, or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically or by other means of stratification' (WHO 2019a). 'Health equity' or 'equity in health' describes the ideal state, in which everyone has a fair opportunity to attain their full health potential and no one is disadvantaged from achieving it. Equity should be a priority focus of health research activities⁵.

New Zealand ethics landscape

When do we need ethical review?

In New Zealand, ethics committees determine their own scope of review, based on the level of risk posed to participants in individual situations. As a general principle, research originating in a tertiary educational institution will normally be reviewed by an institutional ethics committee (IEC) within that institution. However, particular types of research proposals an IEC receives may also come into the scope of a [Health and Disability Ethics Committee \(HDEC\)](#), under section 11 of the [New Zealand Public Health and Disability Act 2000](#). The Ministry of Health administers HDECs.

The function of an HDEC is to secure the benefits of health and disability research by checking that it meets or exceeds established ethical standards. An HDEC's scope of review is set out in its standard operating procedures (Health and Disability Ethics Committees 2018).

⁵ See [Equity of Health Care for Māori: A framework for more information](#)

A research proposal that involves both human and animal subjects requires separate approvals from both human and animal ethics committees. The framework for animal ethics is set out in the [Animal Welfare Act 1999](#).

Researchers must meet relevant ethical standards when they undertake health and disability research in New Zealand, irrespective of whether their work requires ethical review.

Ethical approval from an approved ethics committee (see 'Approved ethics committee' below) is required:

- to provide coverage of participants in a clinical trial who sustain injury, under the [Accident Compensation Act 2001](#), see [chapter 17 on Compensation](#) for more information
- to allow use and disclosure of health information for research purposes where it is either not desirable or not practicable to obtain authorisation from the individual concerned under the [Health Information Privacy Code 1994](#)
- to allow the use of human tissue for research where it is either not desirable or not practicable to obtain authorisation from the individual concerned under the [Human Tissue Act 2008](#)
- for every application approved for funding by the Health Research Council (the HRC), under sections 25 and 31 of the [Health Research Council Act 1990](#).

Ethical review of quality improvement activities

While some level of ethical oversight is necessary, Health and Disability Research Ethics Committee review processes are often not the optimal pathway for review of these activities. Review of activities should ensure that⁶:

- Participants in quality improvement are afforded appropriate protections and respect
- Quality Improvement is undertaken to generate outcomes that are used to assess and/or improve service provision
- Those who undertake quality improvement adhere to relevant ethical principles, law and regulation
- Organisations provide guidance and oversight to ensure activities are conducted ethically including a pathway or process to identify and address concerns.

⁶ Ethical considerations in quality assurance and evaluation activities 2014 <https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities>

The guidance provided in [Chapter 18 Quality Improvement](#) is designed to assist organisations in deciding the appropriate level of oversight for quality improvement. Organisations should consider this guidance when developing policies/advice on quality improvement activities.

Research that uses human embryos and gametes

All applications for research using human embryos and gametes should be submitted to the [Ethics Committee on Assisted Reproductive Technology \(ECART\)](#).

Approved ethics committees

The [Health Research Council Ethics Committee \(the HRCEC\)](#) approves ethics committees to carry out ethical review. To ensure that appropriate standards are met, the HRCEC uses a formal approval process to review and monitor ethics committees (HRC (nd)).

The HRCEC currently approves four HDECs: Northern A, Northern B, Central and Southern. It currently approves 13 IECs:

- Auckland Health Research Ethics Committee
- Auckland University of Technology Ethics Committee
- Lincoln University Human Ethics Committee
- Massey University Human Ethics Committee: Northern
- Massey University Human Ethics Committee: Southern A
- Massey University Human Ethics Committee: Southern B
- University of Auckland Human Participants Ethics Committee
- University of Otago Human Ethics Committee
- University of Otago Human Ethics Committee (Health)
- University of Waikato Human Research Ethics Committee (Health)
- Unitec Research Ethics Committee
- Victoria University of Wellington Human Ethics Committee
- Wintec Human Ethics in Research Group.

For a current list of approved ethics committees, please check <http://www.hrc.govt.nz/ethics-committee-approval-and-annual-reporting>

Complying with New Zealand legislation and international conventions

These Standards are subject to legal constraints. While they 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.

Researchers may face situations in which they experience a tension between the requirements of the law and the guidance of these Standards. In such a situation, researchers should consult with their colleagues or relevant professional body and, if necessary, seek independent legal advice. If researchers are advised that there is a conflict between the law and these standards, researchers should comply with New Zealand law.

Legislation and conventions that may be relevant to researchers include (but are not limited to) the:

- Human Rights Act 1993
- Universal Declaration of Human Rights
- Code of Health and Disability Services Consumers' Rights 1996⁷
- Privacy Act 1993
- Health Information Privacy Code 1994⁸
- 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
- Family Violence Act 2018
- 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 Peoples

⁷ This is a regulation issued under section 74 of the Health and Disability Commissioner Act 1994. It sets out 10 rights applicable to all health and disability services consumers, including those involved in research. Investigators conducting research should be familiar with their responsibilities under the Code, and should consider their study in light of the rights of (proposed) participants. The Code is available on the Health and Disability Commissioner's website (www.hdc.org.nz). Specific rights from the Code are noted at relevant points in these Standards. (Note also that some provisions give legal effect to ethical standards. For example, Right 4(2) states: 'Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards'.)

⁸ This is issued under section 46 of the Privacy Act 1993. It is legally binding and has the status of a regulation. The Code specifies 12 information privacy rules in relation to health agencies and health information, so is applicable to observational studies. It is available on the Privacy Commissioner's website (www.privacy.org.nz).

- Declaration of Helsinki (WMA 2017)
- *International Ethical Guidelines for Health-related Research Involving Humans* (Council for International Organizations of Medical Sciences (CIOMS) and WHO 2016)
- Universal Declaration on Bioethics and Human Rights 2005.

Users' guide

Structure

These Standards are set out in the form of content headings, introductions, standards and commentary. Numbered paragraphs are the standards themselves (eg, 6.7). Commentary that expands on particular standards is identified by a letter corresponding to the relevant standard number (eg, 6.7a).

How to find further information

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

Availability

These Standards are published online only; NEAC will update them as required to ensure they remain relevant and accurate. Check [NEAC's website](#) to be sure you are using the current version. The website will outline any recent changes to the document, and any older versions will be archived.

Primary responsibility for meeting the standards

These standards set out the ethical requirements that:

- researchers must meet or exceed when undertaking health and disability research **and**
- health service providers and disability service providers⁹ must meet or exceed when conducting quality improvement activities.

The Standards apply whether or not research or quality improvement activities require review by an ethics committee.

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

⁹ Health service providers include health service workers, nurses, clinicians and any person involved in quality improvement.

Increasingly, health research and quality improvement involve responsibilities that are broader, extending to institutions and organisations. The Standards primarily use the term 'Researcher' throughout when referring to corresponding responsibilities, however these Standards use the term Researcher broadly, intending to address all those responsible for the conduct of health and disability research, quality improvement activities, data and tissue governance, and any other activity described in the Standards.

Research conducted overseas having human or animal involvement will require appropriate ethics approval from an ethics committee (or equivalent body) in the country concerned, where such a body exists.

Any international collaborative research project that involves researchers in New Zealand or its territories is subject to these standards.

Relationship between these standards and local review procedures

Ethics committees or research offices considering a study will have their own procedures relating to ethical and or local review. These Standards take precedence over any such procedures where the two sources of guidance conflict. In addition, Māori organisations such as iwi may have additional tikanga processes.

Feedback

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

Glossary

See individual chapters for definitions of terms relevant to specific topics, or the [Glossary](#) for a fuller list of terms.

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PART TWO

1 Scope of the Standards

This chapter sets out the scope of the Standards and provides some key definitions.

These standards set out the ethical requirements that:

- researchers must meet or exceed when undertaking health and disability research **and**
- health service providers and disability service providers¹⁰ must meet or exceed when conducting quality improvement activities.

The Standards apply whether or not research or quality improvement activities require review by an ethics committee.

These Standards take a risk-based approach to ethical oversight. Ethical review should be proportionate to the risk proposed by the activity. A low level of ethical scrutiny applied to a research project or quality improvement activity assessed as low or minimal risk does not imply a lower level of adherence to the core principles of these Standards. The intention of the Standards is to ensure adequate protection of participants while reducing unnecessary impediments to, and facilitating the progress of, ethical research.

Quality improvement activities are generally low risk, but nevertheless providers should conduct them according to these Standards. Research can also be low risk, but is often not, warranting higher ethical oversight. See [‘Categories of risk’](#) for further information.

Defining the boundaries of health and disability research

As we as New Zealanders learn more about our own people, we face constant challenges to conventional notions of ‘health’ and ‘disability’ and the inherent limitations

¹⁰ Health service providers include health service workers, nurses, clinicians and any person involved in quality improvement.

of each of those words to adequately recognise the worldviews of all New Zealand society.

That said, this document aims to describe the boundaries of health and disability research. 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. Broadly speaking, health and disability research should:

- aim to answer a question or solve a problem and therefore generate new knowledge to prevent, identify and treat illness and disease
- have the ultimate purpose of maintaining and improving people's health – in the sense of a state of physical, mental and spiritual wellbeing, rather than simply the absence of disease or infirmity
- support disabled people to be included, participate more, exercise choice and control, and be more independent
- address health and disability disparities
- contribute to whānau ora.

This description is necessarily broad; we acknowledge that people's health is influenced by a much wider range of social factors than their health care.

Speaking 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 a human being is 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 about health and disability.

The following activities are not defined as 'research' and are not covered by these Standards.

- **Public health investigations:** these 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 conditions¹¹.
- **Routine public health activities:** these include the use of identifiable data to support delivery of health services, the development of live National Health Index (NHI)-linked data as clinically actionable alerts to responsible clinicians,

¹¹ See 'What makes public health studies ethical? Dissolving the boundary between research and practice' for more information <https://bmcomedethics.biomedcentral.com/articles/10.1186/1472-6939-15-61>

and the regularly investigation, assessment and monitoring of the health status of our resident populations.

- **Public health surveillance:** this involves monitoring risks to health by methods that include systematically collecting, analysing and communicating information about disease rates.
- **Pharmacovigilance (post-marketing surveillance):** this 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). Pharmacovigilance is distinguished from phase IV research, whereby sponsors or researchers conduct clinical research to assess or compare treatments (New Zealand Medicines and Medical Devices Safety Authority 2015).

Quality assurance and improvement

Quality Improvement (prospective process) and Quality Assurance (retrospective process) are slightly different forms of quality initiative. Where the primary purpose of Quality Assurance activities is to assess compliance with accepted standards for an aspect of healthcare, Quality Improvement activities are focused on how an aspect of health care can either be brought up to standard or improved. Quality Improvement therefore involves rapidly repeated, small sample cycles of measurement, analysis and change which continue until the desired improvement is attained. If a Quality Assurance activity identifies a problem, a Quality Improvement initiative may be designed to address it.

¹²In New Zealand in 2003, the Ministry of Health defined five dimensions of quality. These dimensions were underpinned by the foundations of the partnership, participation and protection principles of the Treaty of Waitangi.

¹² See Minister of Health. 2003. Improving quality: A systems approach for the New Zealand health and disability sector. Wellington: Ministry of Health.

Table 1.1 – Five dimensions of quality

| DIMENSION | DEFINITION |
|-----------------|--|
| Safe | Avoiding harm to patients from the care that is intended to help them. |
| Effective | Providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit. |
| Patient-centred | Providing care that is respectful of and responsive to individual patient preferences, needs and values, and ensuring patient values guide all clinical decisions. |
| Efficient | Avoiding waste, including waste of equipment, supplies, ideas and energy. |
| Accessible | Providing care that does not vary in quality because of personal characteristics such as gender, age, ethnicity, geographic location and socioeconomic status. |

Quality improvement activities use a range of tools that include, but are not limited to, clinical audit, process mapping, quality improvement cycles and evaluation. Key principles of quality improvement (Jones et al 2019) include:

- making use of our understanding of our complex health care environment
- applying a systematic approach
- designing, testing and implementing changes for improvement.

Quality improvement and research in health care exist on a continuum of activities concerned with making changes and measuring their impacts with the aim of improving systems, processes and outcomes (Hirschhorn et al 2018). Research aims to develop new knowledge, while quality improvement aims to translate that knowledge into everyday practice through specific methods in a healthcare setting (The Health Foundation 2013).

Researchers, health and disability care providers and health care institutions should consider the ethical dimensions of quality improvement because:

- patients or carers may experience burdens or risks through their participation in these activities
- some patients may benefit from quality improvement activities at the expense of others
- quality improvement activities involve the use of health data
- quality improvement activities can create potential conflicts of interest, when findings indicate shortfalls in care.

- if quality improvement projects are not methodologically sound, resulting knowledge cannot be shared with other health care providers.

As a general principle, people involved in quality improvement activities that share features of ‘research’ as defined (see ‘[Defining the boundaries of health and disability research](#)’) should follow these Standards, where relevant. For example, where quality improvement projects involve accessing and using health information many of the ethical considerations of confidentiality and privacy outlined in Chapter 13, ‘[Health data](#)’, apply. As another example, when a programme evaluation involves patients providing feedback, those conducting it must respect these patients in a manner outlined in these Standards.

Differentiating research from quality improvement

These Standards acknowledge that quality improvement has a lower risk profile than most research, and that healthcare organisations have obligations to conduct quality improvement as part of providing high quality health care for consumers. Quality improvement generally involves implementation of what we already know or reasonably believe to be beneficial. Therefore, it often lacks the elements of risk and uncertainty about impact that research tends to entail, and that necessitate ethical review.¹³

The determination as to whether an activity is ‘research’ or ‘quality improvement’ can assist researchers, and organisations, in determining the appropriate ethical oversight, and has consequences for whether the use of health data is a directly related purpose (ie, clinical audit or service improvement) or a secondary purpose (ie, research). See Table 1. for assistance in determining what an activity is.

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

Publication or an intention to publish a quality improvement activity does not mean an activity is classified as research, does not make it a more than minimal risk activity, and does not alone trigger specific requirement for ethics committee review. Any service provider who intends to publish results of any quality improvement activity should

¹³ See also right 4(4) of the [Code of Health and Disability Services Consumers’ Rights 1996](#): ‘Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer’, and, [Health Information Privacy Code, Rule 11 \(2a\)](#): Disclosure for directly related purpose.

ensure the activity has been conducted in accordance with these Standards and should inform the editor concerned whether ethics committee review is required¹⁴.

Ethics committees in New Zealand do not offer retrospective ethics review. Those conducting quality improvement should ensure they carefully consider whether they plan to publish work in the future, and check publishing requirements before commencing.

See Chapter 18 [Quality improvement](#) for further information, including types of quality improvement activities.

While Table 1. provides some guidance for distinguishing between research and quality improvement activities, it must be emphasised that some projects defy classification within this binary system. Ultimately the level of ethical oversight should be appropriate to the risks of harm from each individual project.

Table 1.2 – Differentiating research from quality improvement

| Human participant research | Quality improvement activities |
|--|--|
| <p>Description</p> <ul style="list-style-type: none"> Activities which attempt to create new generalisable knowledge in response to an acknowledged information gap. | <ul style="list-style-type: none"> Activities which aim to improve healthcare by assessing current situation and systematically implementing/testing evidence -based knowledge within a local organisation. |
| <p>Goal</p> <p>Quantitative research</p> <ul style="list-style-type: none"> Acceptance or rejection of a hypothesis in relation to treatment, cause, risk or diagnosis of a health problem. Small differences may represent a significant finding. <p>Qualitative research</p> <ul style="list-style-type: none"> Description and interpretation of something in its natural setting. May address how treatments and relationships are experienced. | <ul style="list-style-type: none"> Ensure healthcare delivered by organisations are effective, safe, and equitable through the applications of improvement science methodology. |
| <p>Setting</p> <ul style="list-style-type: none"> May be conducted within a healthcare setting or primary research setting. | <ul style="list-style-type: none"> May be conducted within a health and care or community setting |
| <p>Methods</p> <p>Quantitative research</p> <ul style="list-style-type: none"> Emphasis on prespecified aims, clearly protocolised methods, high precision measures, careful bias control, sample size calculations and statistical analysis. May involve random allocation and blinding to intervention. Attempts to remove/minimise contextual influences. | <ul style="list-style-type: none"> Uses established, structured quality improvement methodologies to evaluate baseline performance, implement change and retest for sustained improvement. Approaches include diagnosing and understanding the issue, followed by testing an intervention (usually a known intervention) to ascertain if it results in an improvement in the local context prior to full implementation. Small samples are often adequate. |

¹⁴ This is consistent with the guidance provided in the International Committee of Medical Journal Editors' *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* (2018, section 2.A).

Qualitative research

- Obtains information from interviews, focus groups, observations, or documents or other materials
- Tools to understand the issue may be similar to those used for research such as auditing against a standard and qualitative experience capture through interviews /focus groups/observations. Tests of change are undertaken through PDSA cycles. Methods such as Lean Thinking and Six Sigma are used to identify and remove waste and unjustified variation.
- Group randomisation may occur in cluster or step-wedge designs.

Data collection

- Usually collects data additional to that collected for routine healthcare, sometimes by invasive diagnostic techniques. May also repurpose healthcare data for research.
- Uses existing healthcare data but may require additional data gathering.

Outcomes from activity

- Results published /presented beyond the immediate environment in which they were collected. May be applicable elsewhere. Dissemination may be slow. No presumption that local practice will alter quickly.
- Primary audience is the organisation in which the activity was conducted.

2 Ethical principles

Introduction

This section sets out two sets of principles that collectively form the basis for these standards: Te Ara Tika principles and bioethics principles.

Te Ara Tika is a set of Māori ethical principles that draws on a foundation of tikanga (Māori protocols and practices); 'Te Ara Tika' means 'to follow the right path'¹⁵ and is used in this document as a generic set of principles commonly shared by many generations and communities of Māori; however, they have application to all people in Aotearoa New Zealand (Hudson et al. 2010).

The bioethics principles that appear here have been used in many sets of human research ethics guidelines, which have carefully established and developed their implications.

The principles presented in this chapter represent the ethical sources of the more specific 'musts' and 'shoulds' within the detailed standards in the chapters that follow.

A partnership of principles

These Standards do not ethically or conceptually prioritise either of the two sets of principles. No assumption is made that they cover the same ground in all cases. However, they do have important common ground in one sense: they involve knowledge discovery through respectful and rights-based engagement between researchers, participants and communities to advance health and wellbeing. When used together, the two sets address ethical positions of different societies, thereby strengthening ethical discourse in New Zealand.

These two sets of principles are the ethical sources of the more specific standards set out in the following chapters. For example, the guideline that participants give their informed consent to participate comes from the principle of respect for people, and from the principles of mana and manaakitanga.

¹⁵ See <http://www.hrc.govt.nz/sites/default/files/Te%20Ara%20Tika%20FINAL%202010.pdf>

The principles are guides to support ethical decision-making, and should not be used as rules. In all cases, their use requires consideration of context and a well-reasoned justification.

When the principles are described in the abstract, outside of a specific context, it may become more challenging for researchers to realise them all simultaneously; they may make incompatible demands on researchers. A well-designed research project will mitigate against obstacles and identify necessary solutions.

The principles

Figure 2.1 summarises the two sets of principles. The discussion that follows explains each principle in more detail.

- 2.1 Researchers should consider the features of a proposed study in light of these ethical principles, and should then satisfactorily resolve any ethical issues raised by the study. The application and weighting of these considerations will vary depending on the nature and circumstances of the study in question.

Figure 2.1 – Overview of Te Ara Tika and bioethics principles



Te Ara Tika principles

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

Te Ara Tika principles

Tika

- Tika refers to what is right and what is good for any particular situation. Importantly, in the context of ethics 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 in all studies, regardless of the research design and methods.
- Researchers should engage with communities about which research questions are important, and reflect on the ethical issues associated with their study.

Manaakitanga

- Manaakitanga refers to caring for others, nurturing relationships and being careful in the way we treat others. 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 prevent harmful effects from disclosure of information, prioritise collective participation in establishing the goals and benefits of a research proposal, and empower research partnerships.
- As well as gathering data, researchers should learn to collaborate with and to give back to the community (eg, through koha and sharing ideas).

Whakapapa

- Whakapapa refers to relationships; the term encompasses the quality of those relationships, the reasons for their formation and the structures or processes that have been established to support them.
- Whakapapa in the context of ethics relates to the quality of consultation or engagement process with Māori and the monitoring of the progression of relationships through various stages of the research.
- The relationship between researchers and participants (and New Zealand communities) must involve trust, respect and integrity.
- Whakapapa reminds us that an individual is part of a whānau or wider collective. Often this can infer collective decision-making, collective information sharing, collective participation in consent processes, collective support for research data collection, collective analysis of results and participation in dissemination of results. Researchers need to assess an individual's preferences and to involve their collective support networks.

Mana

- Mana refers to power, prestige, leadership or authority bestowed, gained or inherited individually or collectively. It infers that each individual has the right to determine their own destiny upon their own authority. Mana is an influencing factor in leadership and interpersonal and inter-group relationships, including those entailed in research. Shared knowledge upholds the mana of research participants
- Mana relates to equity and distributive justice in terms of the potential or actual risks, benefits and outcomes of research. In that context it also concerns issues of power and authority in relation to who holds rights, roles and responsibilities. Finally, the principle of mana requires that the research process upholds appropriate aspects of tikanga Māori and respects local protocols.

Bioethics principles

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

Bioethics principles

Beneficence

- Beneficence for individuals and communities implies improving or benefiting people's health or broader wellbeing. It is both the basic aim of good research and its fundamental justification. Health research should be designed, conducted and reported with the intention to improve outcomes. Beneficence also requires that projects have merit.
- The idea of 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.

Non-maleficence

- Non-maleficence requires researchers to avoid causing harm to individuals and communities, or to cause the least amount of harm possible.
- 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 them with a compensating benefit.
- Researchers must put appropriate measures in place to minimise the risk of harm, and effectively respond to any harm to individuals and communities.

Respect for people

- Respect for people underlies the general human rights principle of autonomy but is also significant in cases where autonomy – and, in particular, a person's capacity to exercise informed consent – is reduced.
- Autonomy itself is a broad concept, encompassing individual autonomy but also relational autonomy and interdependence, and privacy. Autonomy also comprises the rights and interests of groups and communities.
- In many cases in the context of health research, 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 by which researchers can respect participants' autonomy is by seeking their free, informed and ongoing consent.
- A person's autonomy may be affected by their capacity to make an informed choice or give informed consent. This can change over time and can depend on the nature of the decision and any changes in the person's condition and context. Diminished capacity may be permanent or temporary. A wide conception of autonomy is necessary, to reflect the diversity of available decision-making methods.
- Where a person is not able to make a decision for themselves, even after support has been offered, further measures are necessary to protect their interests and respect their wishes.
- In some cases, seeking informed consent would prevent or skew ethical research (e.g. where huge data sets are involved). In these cases, researchers are nonetheless expected to respect the people concerned, by treating their data with care.

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 in health outcomes for specific groups (e.g. particular socioeconomic or ethnic groups). In determining research questions and processes, researchers should consider how the research could reduce inequities in health and wellbeing. Researchers should also consider whether the research could increase inequities, and, if so, how they will mitigate this potential effect.

3 Research and Māori

Introduction

There are significant inequities in health status between Māori¹⁶ and other New Zealand populations. Some reasons for these inequities are:

- the historical and persistent consequences of colonisation, whereby Māori were subjected to dispossession of their land; appropriation of resources; alienation from their culture; and the disruption of their traditional relationships, responsibilities and practices
- unequal 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)
- unequal access to health and disability services
- differences in the quality of care Māori receive compared to other groups.

These persistent and significant health inequities have been longstanding and described as a breach of the Treaty of Waitangi, and as avoidable, unethical and unjust. This substantiates a focus on eliminating Māori health inequities and honouring Māori health aspirations in the ethical review of all health research.

The importance of health and disability research with Māori

All research in New Zealand is of interest to Māori. All studies may produce benefits for Māori, but may also present risks of harm. All research has the potential to support Māori achieve their aspirations. All researchers in New Zealand therefore must consider the degree to which they can contribute to improving Māori health outcomes.

3.1 Researchers should maximise the degree to which their study can contribute to Māori health outcomes.

¹⁶ Māori are the indigenous people of New Zealand. Globally, Nations across the world are increasingly recognising indigenous rights; key guideline documents on this subject emphasise self-determination; the protection of heritage, indigenous knowledge, plants and genetic material; and the right for indigenous people to 'maintain and strengthen their distinct political, economic, social and cultural characteristics' (as stated in the United Nations Declaration on the Rights of Indigenous Peoples).

- 3.2 Research should include Māori participants unless there is a valid justification where the research excludes Māori.
- 3.3 Research design must demonstrate cultural rigour in order to meet ethical requirements.
- 3.3.a Cultural rigour considers, amongst other things, the application of cultural concepts, norms, practices and language in the research process that actively protect Māori individual and collective rights. Cultural rigour can be ascertained by conversations with Māori, especially experienced Māori health researchers who understand the purpose of rigour in research contexts.
- 3.3.b Researchers must answer certain questions right from the start of developing their study:
- What might this research offer to Māori communities?
 - What questions should the research try to answer to improve the wellbeing of Māori communities?
 - What methods are best to use to conduct research with Māori communities?
- 3.3.c If the researcher is of non-Māori descent, the researcher must answer these questions first:
- Am I the right person to be doing this study, and why?
 - In what ways does my cultural position help or hinder this study?
 - Do I have any conflicts of interest that impact my objectivity?
- 3.4 Researchers must act with integrity and transparency when conducting research involving Māori.
- 3.5 When they are conducting a study with a particular whānau, hapū, iwi, community or organisation, a partnership approach should underpin the development of the research proposal as well as the research design and all elements of its implementation.
- 3.6 Researchers should consider Māori data sovereignty and its implications for their research.¹⁷
- 3.6.a Māori data can include, but is not limited to, data about Māori organisations and businesses, data about or derived from Māori (such as biological samples) that is used to describe or compare Māori, and data about te ao Māori (the Māori world) that emerges from research.

¹⁷ See the website of Te Mana Raraunga, the Māori Data Sovereignty Network.

- 3.6.b Any data collection in relation to Māori should be collected in a way that aligns with the Treaty of Waitangi and Māori fulfilment of their own rangatiratanga, or self-determination. Involvement of Māori in research design, collection, analysis, interpretation, and management of their own data is essential.
- 3.6.c All researchers must clearly identify the Māori collective (whānau, hapū, iwi, organisation) or the Māori stakeholder group they wish to engage by specific recruitment criteria (eg, 'Māori men with diabetes accessing diabetes services in X District Health Board', 'Māori mothers under the age of 20 living in X city with experience of Y').

Consultation

Consultation, in its simplest form, starts with a conversation. An initial conversation can allow researchers to establish rules for engagement, as a first step toward establishing cultural understanding (HRC 2010).

Consulting early can improve the quality of the data ultimately produced in a number of ways (eg, it can result in better recruitment, a more meaningful research question or clearer outcomes). In this way, the results from health research involving robust consultation can contribute to improving the health status of Māori and benefit all New Zealanders.

3.7 In the case of international clinical trials, the protocol is often designed overseas and being applied to a New Zealand context with limited opportunity for alteration. Even so, researchers should make every effort to adapt the protocol, or local study processes, as necessary to the New Zealand context.

- 3.7.a In the case of international clinical trials, it is expected that engagement with Māori will be achievable at the New Zealand investigator and clinical trial site level¹⁸.

Partnership: engaging and consulting early

Under the principle of manaakitanga, all health researchers should engage in consultation. Early engagement with Māori health researchers (eg, institutional colleagues), even at the point of the conception of a research idea, can be valuable to research teams, and help them to identify opportunities and challenges in the development phase of a research project. Early engagement can prevent problems

¹⁸ A trial site or 'locality' is an organisation responsible for a hospital, health centre, surgery, or other establishment or facility at or from which the procedures outlined in the protocol of a study are to be conducted.

further along the research process, including ethical concerns. Māori expertise on Māori methodologies or methods is compulsory.

Conversations with Māori stakeholders open the door for researchers to understand the most effective and efficient pathways for working alongside Māori participants. This can be as simple as inviting and including Māori colleagues in discussions about the research question, design, governance and conduct, as well as the analysis and dissemination of research findings. While casual engagement with colleagues is often valuable, researchers must take care not to overburden individual Māori colleagues. Institutions should invest in their Māori research capacities to facilitate formal consultation, so that meeting the requirements of engagement and consultation is not overly burdensome. Research projects can contribute, and have contributed, to building Māori research workforce capacity, through training opportunities.

Research involving a process of consultation in which Māori are regarded as equal partners in the research design will provide much greater outcomes than research in which Māori play no part in framing the research question, and especially if the diverse realities of Māori, and Māori opinions, are not reflected in the analysis and research results. Meaningful engagement with Māori involves their active participation, and a research process in which Māori values and views are evident throughout.

Meaningful engagement can evolve into long-term relationships. New Zealand has produced important research involving Māori as participants, as a result of Māori leaders approaching researchers to help them find answers to particular health concerns. Equally, researchers may approach Māori to help them find answers to health problems.

3.8 Researchers should consider the amount of time required for partners/participants to consider their potential involvement in the research, and assess whether they will have a meaningful role. Researchers must ensure they have the appropriate resources (including time) to become familiar with the processes, prospects, risks and benefits of the research proposal with the Te Ara Tika principles in mind.

Degrees of consultation

Different levels of Māori involvement, different research topics and different levels of risk to Māori may require different levels of consultation. The following examples of Māori involvement in research move from the lowest to the highest level of involvement, and set out minimum expectations for engagement with Māori.¹⁹

¹⁹ See Hudson et al 2010 for discussion of what each level of consultation involves, and the questions that researchers should consider. See also 'Table 1' of the joint CCDHB and ADHB Framework for Māori Review of Research in District Health Boards and the University of Otago Research Consultation with Māori Policy

Māori involvement in research and minimum expectations

General guidelines

- Apply to all research undertaken in New Zealand, including research not involving Māori

Minimum expectations

- Local or institutional review that confirms any exclusion of Māori is valid and justified.
- Researchers should undertake self-assessment as to whether their research adheres to the principles of the Treaty of Waitangi.
- Māori as tangata whenua have manaakitanga responsibility over all people in New Zealand; researchers should explore how all research relates to the Treaty.

Research involving Māori

- May involve Māori as individuals or collective participants, Māori data or researchers, or study outcomes that have relevance for Māori. This includes Māori as part of general population research.

Minimum expectations

- Local Maori review processes must confirm that the design, methods and analysis of the research are appropriate for Māori as individuals and the collective(s)²⁰.
- Māori ethnicity data must be able to be extrapolated from a general sample in cases where statistically and ethically sound.
- If analyses by ethnicity is planned, Māori samples must be statistically representative.
- If a collective/community of Māori is involved:
 - Researchers must define the specific Māori collective/community of interest for their research.
 - Consultation with the collective/community must occur at the earliest stages of development of the research design.
 - Formal support from an appropriate mandated leadership/governance entity for the named collective. For example, a particular iwi's governance organisation must endorse or approve research involving that iwi.
 - Collective approval processes are generally more complex and mana-enhancing than conventional mainstream ethical review.

²⁰ Researchers who do not have access to institutional Māori review processes can contact individual Māori researchers via the Māori and Indigenous Researcher Directory Te Hononga Pūkenga.

Māori involvement in research and minimum expectations – continued

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 methods and non-Māori researchers, but will involve a high level of cultural integrity. In other words, there is purposeful and planned oversight by Māori research colleagues and/or advisors. This type of research often has dual accountability – to both non-Māori (eg, an institutional body such as a university) and Māori. It commonly produces knowledge outcomes that are measured against non-Māori and Māori research standards and practices.

Minimum expectations

- Māori researchers must be a part of the research team.
- Institutional ethics approval must include Māori scrutiny that confirms that the design, methods and analysis of the research are appropriate for Māori as individuals and the collective/s.
- Māori ethnicity data must be able to be extrapolated from a general sample, in cases where statistically and ethically sound.
- If a collective/community of Māori is involved:
 - Researchers must define the specific Māori collective/community of interest for their research.
 - Consultation with the collective must occur at the earliest stages of development of the research design.
 - Formal support from an appropriate mandated leadership/governance entity for the named collective. For example, a particular iwi's governance organisation must endorse or approve research involving that iwi.

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. In carrying out kaupapa Māori research, researchers use a broad range of research methodologies to fulfil their objectives.

Minimum expectations

- Research is led by Māori and addresses issues of importance to Māori using Māori methods of conduct and analysis.
- All of the minimum expectations set out above apply.

Sharing benefits of research

Te Ara Tika principles necessitate sharing the benefits of research.

When researchers are considering their research in terms of its ethics, part of their task is to understand the nature of the potential 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).

- 3.9 Researchers should consider the potential benefits of their research for Māori participants and their communities.
- 3.10 When considering how Māori can benefit from research, researchers should review the previous incidence, intervention rates, outcomes and prevalence (statistics) of the disorder under study (or treatment indication, if the research is a drug trial) in Māori.
 - 3.10.a Research on many disorders is particularly important in the context of Māori health, while a very few are relatively rare in Māori and have less of an impact on Māori populations. Prevalence is an important factor, but researchers should also consider health outcomes: some disorders may have a low prevalence among Māori, or prevalence equivalent to national prevalence, but worse outcomes.
 - 3.10.b Researchers must be honest and open about all parts of their research, including their publication plans and how they (as researchers) will personally benefit from undertaking the research.
- 3.11 If research has an impact on Māori health, the research protocol should include information on how researchers will ensure that Māori benefit at least equally (and how Māori will gain a greater benefit than the general population will if Māori are to gain more benefit than the general population).
 - 3.11.a Researchers should consider what extra measures they can put in place to ensure that Māori participate (eg, iwi consultation, inclusion of Māori researchers, active follow-up), to involve them in interpreting results or study findings, and to share their findings with those consulted in an appropriate way.

4 Research and Pacific peoples²¹

Introduction

Many Pacific individuals and families continue to experience health disparities and face financial, cultural, logistical, physical and linguistic barriers to their access to and use of services across the health and disability sector (Ministry of Health 2014a).

These barriers are key reasons why Pacific peoples are not benefiting from health services as much as other groups (Tobias and Yeh 2009). One strategic priority of the New Zealand Health Research Strategy (Ministry of Business, Innovation and Employment and Ministry of Health 2017) is to 'invest in research that results in equitable outcomes for Pacific peoples and helps them to lead independent lives'.

The term 'Pacific peoples' does not refer to one homogeneous group of people. Rather, it refers to 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; the term includes people born in the Pacific region and those of Pacific heritage who were born in New Zealand. These Standards use the term 'Pacific peoples'; the terms 'Pasefika' (Samoan), 'Pasifika' (Niuean and Tokelauan) and Pasifiki (Tongan) are also used in Aotearoa New Zealand.

Pacific communities have an integrated and holistic perspective of health and wellbeing. Pacific concepts of health include an interconnectedness between beliefs and values, as well as between cultural, spiritual, emotional and social aspects, and a view that health and wellbeing are often influenced by family and community, specifically in relation to health and illness. Pacific health research must be underpinned by an understanding of these concepts, and should be aimed at obtaining data that has the power to identify and reduce inequity across populations, improve Pacific health outcomes and strengthen the Pacific health and disability workforce.

Pacific health research creates knowledge and understanding essential for improving the health of Pacific peoples, improving health equity and creating healthy Pacific communities. Pacific research encompasses various approaches to integrating cultural worldviews, beliefs, practices and concepts, including indigenous Pacific knowledge

²¹ The term 'Pacific peoples' is unique to use in New Zealand by government agencies to denote peoples, other than Māori, who were born in and/or reside in New Zealand and they are descendants of nations from within the Pacific Ocean.

systems, conceptual frameworks and models of health such as fonofale (Pulotu-Endemann 2001). Pacific frameworks and methodologies provide for the perspectives of Pacific peoples to be engaged with and represented in culturally appropriate and meaningful ways. In research that targets the Pacific population, relevant Pacific groups should participate in all levels of decision-making about and implementation of the study and dissemination of results.

These Standards highlight significant issues that researchers of both Pacific and non-Pacific ethnicity should be aware of when conducting research with Pacific peoples. The Standards promote research that empowers both researcher and researched. They acknowledge that Pacific studies will be diverse, and that researchers should frame them and shape them according to changing Pacific contexts, and the context of the research. Specifically, these Standards focus on the consultation process for research that involves Pacific peoples or addresses their health and disability concerns, prioritising meaningful and reciprocal engagement.

The importance of health research with Pacific peoples

Pacific peoples use both Pacific and non-Pacific primary health care services. Pacific primary care or community-based providers include general practitioner (GP) services, disability support services and mental health providers. Capacity and capability building is critical to improving Pacific health outcomes through research (Ministry of Health 2014a).

Many Pacific individuals and families continue to experience health disparities and face financial, cultural, logistical, physical and linguistic barriers to their access to and use of services across the health and disability sector. These barriers are key reasons why Pacific peoples are not benefiting from health services as much as other groups. Therefore, it is important that research contributes to enabling Pacific peoples to lead longer, healthier and more independent lives and ensuring that Pacific peoples realise their right to health equity.

- 4.1 Researchers should acknowledge that Pacific people's engagement in health research can be influenced by many factors, including:
 - Pacific values and worldviews of disease and disability
 - whether the research methodology, ethics and approach demonstrate cultural integrity with respect to Pacific cultural perspectives, norms, values and attitudes, including those of Pacific peoples born in the Pacific Islands region and those born in New Zealand

- whether there is a strong and genuine relationship, based on trust, between researchers and Pacific leaders and communities.
- 4.2 Researchers must ensure that their research involving Pacific peoples has cultural rigour; that is, that it involves Pacific peoples at an early stage in the research design, and in the governance, management, implementation and analysis of the research.
- 4.3 Researchers must ensure that their research involving Pacific peoples is conducted in safe and enabling research environments that demonstrate competent practice by:
- seeking ethnic-specific and context-specific advice on culturally competent practice
 - communicating appropriately translated information to Pacific peoples.
- 4.4 A research protocol must demonstrate cultural rigour, and be developed only after the researchers have established meaningful and reciprocal engagement with ethnic communities involved.
- For research to have cultural rigour researchers must:
- consider what cultural principles and values, norms, practices and language are important in the research process.
 - consult in ways that establish meaningful and reciprocal relationships that are genuine and sustained throughout the research life cycle.
- 4.5 Pacific health research protocols must describe how the study will address the inequities in health outcomes that Pacific peoples face.
- 4.6 Researchers involved with Pacific peoples must understand Pacific dimensions of health (eg, family, spiritual, emotional, physical and environmental dimensions) and how these dimensions interact. To enrich their understanding, researchers should engage Pacific partners, including consumers/service users and family leaders, throughout the life cycle of their research.
- 4.7 In the case of research that involves a specific Pacific community, researchers must consult with that community's leaders when designing the research. Researchers must carefully consider who it is best to engage with, to ensure that those involved have sufficient knowledge to play a meaningful role.
- 4.8 In the case of research involving significant participation of Pacific peoples or that will have a significant impact on Pacific peoples, researchers must seek the

appropriate involvement of a Pacific researcher, expert or advisory group with Pacific representation.

- 4.9 Researchers must give Pacific peoples adequate opportunities and resources (including time and translations and interpreters as necessary) to allow them to become familiar with the processes and potential risks and benefits of the research.
- 4.10 Researchers must respect Pacific people's rights and interests in relation to data and knowledge, and take protective measures to safeguard indigenous Pacific knowledge and knowledge holders appropriately.

Pacific dimensions of health

Where research involves Pacific peoples or addresses health and disability concerns of importance to Pacific peoples, researchers should build their cultural knowledge of Pacific communities and their values, especially those key concepts and principles that promote wellbeing along a continuum that acknowledges the physical, spiritual, mental, psychological and emotional dimensions of human beings. In general, within the Pacific worldview, wellbeing is achieved when all aspects of an individual and collective are in balance, in harmony and integrated, and co-exist with environments, kinship and support systems, language, the fulfilment of roles and responsibilities, and a recognition of mana and tapu (Peteru 2012).

- 4.11 Researchers involved with Pacific peoples should seek strong and enduring engagement with Pacific communities and consumers, to ensure research responds to the health needs of Pacific peoples. They should undertake consultation with appropriate community leaders, including those active in serving Pacific peoples in churches, clubs, academia, elder communities and youth communities; Pacific health experts; and Pacific providers and services.

Engagement

Pacific research methodologies provide good-practice examples of how to engage with Pacific consumers and communities in a New Zealand context. For example, the talanoa methodology (United Nations Framework Convention on Climate Change Secretariat 2018), acknowledges the importance of respect, respectful spaces and relationships when undertaking research.

- 4.12 When involving Pacific communities, researchers should incorporate reciprocity (eg, the exchange of skills and resources with data, knowledge and wisdom) as a way of establishing good relationships between themselves, participants and the community, ensuring safety and avoiding exploitation and harm (HRC 2014b). Researchers must 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, researchers and participants must be aware of confidentiality and privacy.
- 4.13 Meaningful and reciprocal engagement aims to establish and maintain long-term relationships. Researchers should expect to be asked to give back to the community in culturally appropriate ways before, during and after their research. Researchers should:
- understand that effective face-to-face consultation is critical to establishing meaningful relationships with and among Pacific people
 - consult in ways that ensure the acceptance, legitimacy and relevance of the research, and create meaningful opportunities to contribute to decision-making
 - ensure that the dialogue between researcher and participants, and the mutual relationship, continue at every stage of the research
 - identify all groups of people relevant to the research with whom they should consult
- 4.14 Researchers should aim to disseminate their research findings widely and spread knowledge, awareness and understanding of Pacific health issues, to support provider development and implement health policies emanating from research.

5 Disability research

Introduction

Research involving disabled people is as important as research with all other groups. As with health research more generally, equitable access is crucial to ensuring that disabled people receive the benefits of research and are given every opportunity to participate (United Nations Convention on the Rights of Persons with Disabilities 2006).

At present, there is a lack of data about disabled people, their lives, and their needs that would allow researchers to meet their obligations to disabled people. This indicates a problem of research access for disabled people. In 2013, 24 percent of New Zealanders identified as disabled;²² this inequity therefore represents a significant gap in our collective knowledge. Disability research has a role to play in this regard: it focuses on our ‘disabling society’, and on the enabling, rather than the curing, of people living with impairments.

The history of exploitation in research involving disabled people means that researchers must carefully consider how they conduct research in this area. Researchers must achieve a balance, respecting a disabled person’s right to access research and its benefits on the one hand, and being aware of the potential for exploitation on the other. Paternalism and exploitation are avoided when researchers align their conduct with the general principles laid out in Article 3 of the [United Nations Convention on the Rights of Persons with Disabilities 2006](#) (the Convention), which are referenced throughout this chapter, and the Te Ara Tika principles.

- 5.1 Researchers must recognise the intersectionality of human identity, and that some people identify with multiple ethnicities and social groups, including disabled people. Disabled people are inextricably situated within other groups, for example tāngata whaikaha (disabled Māori).
 - 5.1.a Researchers should recognise that women, those from the LGBTQI community, and indigenous groups with impairments are subject to multiple forms of discrimination, and strengthen measures to ensure their full and equal enjoyment of human rights in line with the Convention’s call for “Non-discrimination” ([United Nations Convention on the Rights of Persons with Disabilities 2006](#)).

²² 2013 census.

Distinguishing disability research from health research involving disabled people

The ‘social model’, as the basis of disability research, recognises that people are *impaired* by their bodies and *disabled* by their social and built environments; disability is not something possessed by the individual, but something imposed by an exclusive society. The social model holds that disability occurs when one group of people creates barriers by designing a world only for their way of living, and taking no account of the issues faced by other people. There are of course other frameworks for understanding disability. Other examples include the identity model, where disability is thought of as an identifier like sex or ethnicity, and the economic model, which positions disability as a challenge to an individual’s productivity (Retief and Letšosa 2018). However, at the backdrop of health and disability research ethics, the social and medical models of disability are the focus of this chapter.

It is therefore important to outline the difference between disability research, which focuses on a particular disability issue arising from the social environment, and research involving disabled people which may be medical or rehabilitative by nature (‘health research’). For example, medical interventions which appropriately target impairments may do little to address non-biological causes of disability. There is obviously a great need for health research involving disabled people, but it is imperative that researchers never cast disabled people only as subjects to be ‘treated’ or ‘cured’. Researchers should always acknowledge that disabled people are not just passive bystanders in the research process, and have many contributions to make both as researchers and participants. While the Standards in this chapter apply to both health research and disability research, many provide specific guidance on the latter.

The level of reciprocity in the research process will be greater in disability research, so it is important for researchers to identify when they are following a social methodology or an individual medical model of disability. The main departure of disability research from impairment-based health research is an understanding of “social potential [as] not dependent on correcting the disabled body, but instead made possible through institutional and material change.” (Williamson 2015)

Disability research redirects focus away from the impaired individual, allows its participants to take on a leadership role in removing social barriers, and has the ability to empower disabled researchers and participants. Research also acknowledges and validates disability issues, examines innate and naturalised biases, encourages enabling rather than disabling attitudes, and fosters respect for the “difference and

acceptance of disabled people as part of human diversity and humanity” (United Nations Convention on the Rights of Persons with Disabilities 2006).

The importance of recognising the social determinants of disability has been recognised internationally. Under the [United Nations Convention on the Rights of Persons with Disabilities 2006](#), there is a general obligation on states parties ‘To undertake or promote research and development of universally designed goods, services, equipment and facilities...which should require the minimum possible adaptation and the least cost to meet the specific needs of a person with disabilities’ and ‘To undertake or promote research and development of...new technologies, including information and communications technologies, mobility aids, devices and assistive technologies, suitable for persons with disabilities’ (Ibid.).²³ Research in New Zealand has a responsibility to address the problems confronted by disabled people in a way which respects the social origins of those problems.

Study design and consultation

Historically, there has been a significant [power imbalance](#), beyond even the usual asymmetry between the researcher and the researched, in the relationship between researchers and disabled people. Social inequities maintain this imbalance to varying degrees. It is therefore of high importance that disabled people are involved in study design whenever and however possible, in line with Article 4.3 of the Convention. Researchers should be alert to the fact that disabled people are sometimes excluded, and failed to be included, in research designs intended to cover a ‘general’ population (Iphofen 2009).

Their primary aim should be [co-design](#); that is, research that is designed in collaboration with disabled people themselves. Co-design fosters trust and builds relationships with participants, which is a fundamental part of ethical research.

5.2 Researchers should strongly consider a participatory approach when conducting disability research, whereby appropriate engagement with prospective participants and relevant stakeholders helps them frame research questions, devise methodology, interpret findings, avoid an ‘ableist’²⁴ bias, and improve the overall efficacy of the study (National Disability Authority 2009).

²³ Article 4.

²⁴ “Ableism is a set of beliefs or practices that devalue and discriminate against people with physical, intellectual or psychiatric disabilities and often rests on the assumption that disabled people need to be ‘fixed’ in one form or the other” – Center for Disability Rights <<http://cdmns.org/blog/uncategorized/ableism/>>.

- 5.2.a Researchers should consider the importance of a disability advisory group or researcher when reviewing the research design for disabling aspects.
- 5.2.b Researchers should not use participatory approaches at the expense of scientific validity. However, the social focus of disability research makes co-design highly important (ibid.).
- 5.3 Researchers should consult with disabled people and relevant stakeholders, such as disabled people's organisations, when their research focuses on a disability issue, following the maxim: 'Nothing about us, without us.'
- 5.3.a For example, researchers may need a disability perspective when developing an algorithm to diagnose an impairment.
- 5.4 Researchers should consult with disabled people early in the design process, to ensure that their study is best placed to answer the research question. Consultation and/or collaboration is more likely to result in effective and ethical research, enhance well-being, prevent harmful assumptions or bias, and reduce stigmatisation.
- 5.4.a Collaboration is also beneficial in that it can build the research/participation capabilities of disabled people.
- 5.5 Researchers should consider ways in which disabled people can be included in their research strategy (see Chapter 11 [Research conduct](#)), taking into account:
- the method, length and intensity of participation they seek, and whether this can be adapted to the needs of disabled research participants
 - the sampling strategy, and whether it allows a diversity of disability to be represented
- 5.6 Regardless of the level of co-design and consultation researchers decide on, researchers should appreciate that research is a reciprocal relationship. At the very least, disabled people should benefit from research they are involved in, and their expertise and time should not be taken for granted. It may be appropriate for researchers to offer participants a koha.
- 5.7 Researchers should understand the cost of disability research, and that in order to be of benefit to disabled people it is likely to incur greater cost than other forms of research, given that facilitating the inclusion of disabled participants may be more complex. Researchers need to have sufficient financial resources to ensure that their research is ethical, taking into account activities before, during and after the research.

- 5.7.a Current funding models often do not allow researchers to adequately communicate with the communities they are researching.
- 5.7.b Researchers should be aware that the recruitment of participants into disability research has been historically difficult, and may take more time than the equivalent process in other kinds of research. Study timeframes should allow for this, and recruitment approaches must accommodate the needs and lifestyles of disabled people.
- 5.8 Some disabled people are approached for research on a regular basis, and researchers must be cautious of research fatigue.
 - 5.8.a Researchers should also be aware that disabled people's organisations are frequently asked to share research information and identify participants, but do not always have the necessary resources to do so.

Informed consent and facilitating participation

Article 12 of the Convention requires that disabled people enjoy equal recognition as persons before the law, and the rights that this entails. Like all research participants, disabled people should be safeguarded from extortion and undue influence, though this must be proportional to the degree to which it affects a person's ability to act on their will and preferences (United Nations Convention on the Rights of Persons with Disabilities 2006).²⁵ Researchers will need to weigh protective measures against disabled people's right to take risks when engaging in life experiences, and demonstrate a respect for "inherent dignity, individual autonomy including the freedom to make one's own choices, and independence of persons (Ibid.)."²⁶

- 5.9 As a default position, researchers should take all people, regardless of disability, as having the capacity to provide informed consent²⁷.
- 5.10 Where researchers have reasonable grounds to believe that a disabled person cannot by themselves give informed consent, they should provide that person with access to the support required to do so. It should be noted that almost any person, with the right support, is capable of providing informed consent.
- 5.11 A person-centred, supported decision-making model should involve:
 - providing information to each potential participant on an individual, face-to-face basis

²⁵ Article 12.

²⁶ Article 3.

²⁷ See Right 7(2) of HDC Code of Rights

- allowing adequate time for the process of obtaining informed consent
- delivering information in a form appropriate to the individual concerned, for example through tailored patient information sheets and consent forms that researchers have trialled with a group of people who are similar to the potential study participants
- if the individual is unable to read or write, using verbal or alternative methods of communication to convey information and record informed consent
- taking into account factors such as level of understanding, reading ability, and knowledge about research and research requirements
- involving members of the individual's support network, while ensuring that potential participants experience no coercion in making their decision on whether to take part in the research
- in the case of children with disabilities, providing assistance aligned to their identification as both a child and a disabled person
- if necessary, hiring a qualified person to conduct the supported decision-making process²⁸
- keeping a permanent record of the process, as evidence that information was provided in an appropriate manner and informed consent was obtained without coercion.

5.11.a For the purposes of these Standards, there are three groups of people researchers should consider when obtaining informed consent: **1)** those who can give informed consent, **2)** those who require assistance to give informed consent, and **3)** those who cannot give informed consent. An unconscious person is an example of someone who cannot give informed consent, and marks the limit of the supported decision-making model.

5.12 The level of oversight of the process of determining an individual's capacity to consent should be proportional to the risks and complexity of the research. Disability research is social research, so clinical oversight may not necessarily be required. However, the determination should be evidence-based and, where possible, external; leaving this decision entirely to the researcher may introduce bias.

5.13 Researchers should take steps to accommodate the specific needs of disabled people, to make their research accessible and promote inclusivity. These steps could include:

- preparing large-print information and consent forms and, when necessary, audio tapes or live-read material

²⁸ For example, the IHC (ihc.org.nz) provides intellectual disability support services and holds workshops on supported decision-making.

- providing documents in easy-to-read or alternative formats, including that which interface with participants' assistive technology
 - providing support for participants with hearing-related needs (e.g., signage, sign-language interpreters, braille, and hearing loops)
 - communication methods which accommodate neurodiversity
 - ensuring that research venues are physically accessible
 - ensuring that the study (and results) are accessible
- 5.14 Researchers should ensure they themselves are accessible, and that they supply all participants with a means of making contact with the study team. Researchers should not assume that participants have mobile phones or email addresses.
- 5.15 Researchers should ensure that people are equally eligible to participate, regardless of their disability or any other aspect of their identity.
- 5.15.a For example, if disabled people are to benefit from new medicines, they should be able to participate in clinical trials. Likewise, if disabled people are subject to a particular public policy, they should be able to participate in relevant qualitative research.
- 5.15.b Moreover, researchers should acknowledge that disabled people have much to give in research, and that a lack of fair representation is to the detriment of the public good.

Disability research data

The analysis and dissemination of data is an important part of the research process, and is how New Zealand will fulfil its obligation to remove social barriers and further empower disabled people. Central to the ethical treatment of disability data is the Convention's principle of "Accessibility" (United Nations Convention on the Rights of Persons with Disabilities 2006).²⁹

- 5.16 Researchers should ensure that they disseminate their research findings in a way which reaches the group they are engaging with. Dissemination is part of the research process and must be conducted under the same ethical principles (see '[Communicating and disseminating research results](#)').
- 5.17 Researchers should publish the results of disability research in open-access journals. They should limit sponsor publication requirements wherever possible,

²⁹ Article 3.

and ensure that data that is of relevance to a disability issue is not concealed by a paywall.

- 5.17.a Concerns around intellectual property should not limit disabled people's access to disability research data. The Marrakesh Treaty (2013), for example, calls for relevant works to be publicly available, in an accessible format, to disabled people.
- 5.18 Researchers should be conscious of the digital divide (the gulf between those with easy access to the internet and those without it), especially in disability research. It should not be assumed that everyone has access to specific technologies, such as mobile devices, and poverty barriers should be considered. Availability does not imply accessibility.
- 5.19 Researchers should publish their data in an accessible format in both digital and physical forms, taking into account the specific needs of disabled people.
 - 5.19.a Researchers should consider making large-print documents, and not just standard PDFs, available.
- 5.20 Researchers should disaggregate data as appropriate and use it to meet the obligations outlined in this chapter, and to address the barriers faced by disabled persons in exercising their rights (United Nations Convention on the Rights of Persons with Disabilities 2006).
- 5.21 Researchers should be cognisant of the potential harms of reporting, and take care in interpreting and publishing study results. Researchers should give due consideration to whether they have answered their study question.
- 5.22 When using artificial intelligence in disability research – for example as a diagnostic tool – researchers should consider the limitations and potential biases of AI systems, and take the associated ethical issues into account (see [‘Health data and emerging technologies’](#)).
 - 5.22.a The use of big data such as Statistics NZ’s Integrated Data Infrastructure in disability research is not without its problems. Definitions themselves can be disabling. If researchers inadequately define ‘disability’ for their purposes, then the results of big data research may be inaccurate or even harmful for disabled people. Disabilities do not exist in isolation, but they occur in tandem with other social problems. Researchers must take care when examining the cause of a social problem to avoid identifying a ‘disability problem’ where one does not exist.

Disabled people as researchers

Disability research in particular benefits from the involvement of disabled researchers, who bring credibility and authenticity to their projects. However, there is currently a paucity of disability research conducted by disabled researchers. Economic models can be structurally biased when focussed solely on medical productivity, causing unequal access for disabled researchers. Additionally, the higher costs sometimes accrued by disability research are a barrier. To encourage ethical disability research, disabled researchers need to be economically enabled to enter the research field and to conduct their studies.

- 5.23 Whether it is focused on a disability issue or not, research conducted by disabled people should give due consideration to the study design, and to the reasonable accommodations needed for disabled researchers to be successful in their work.
- 5.24 Where appropriate, those involved in the research design should consider engaging support workers to carry out tasks relating to the research, as an extension of disabled researchers' autonomy.
- 5.25 Disabled researchers should receive support to navigate the research space free of discrimination.

6 Ethical management of vulnerability

Introduction

This chapter provides ethical guidance unique to individuals in a vulnerable situation. 'Vulnerability' in this context refers to a substantial incapacity to protect one's own interests owing to impediments such as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group (CIOMS and WHO 2016).

Vulnerability may vary over time; people may be considered vulnerable at some stages in their lives but not in others. Vulnerability is both universal and specific. Researchers need to take into account what people are vulnerable to, and whether and how research might create, exacerbate or otherwise interact with participants' existing vulnerabilities (Lange et al 2013; Rogers and Lange 2013).

Research with vulnerable individuals is necessary, to answer questions that are important to people with similar characteristics. Such research is often crucial in reducing the health inequities experienced by these groups. For this research to meet the ethical principles of justice and mana, researchers should ensure that vulnerable individuals or groups are not a convenience sample; the group must stand to benefit from the knowledge, practices or interventions that result from the research. Research should be conducted in partnership.

The ethical principles of respect for people and whakapapa require researchers to pay attention to the rights of all participants, taking particular account of potentially vulnerable people whose individual characteristics and circumstances, in the context of the study, place them at increased risk of harm.

Researchers must avoid excluding groups of people based on stereotypes. A person's individual vulnerability depends on context as well as group characteristics, and can vary according to 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 appropriately.

Balancing access to research with avoiding exploitation

- 6.1 Researchers should not exclude participants from research simply because they may be vulnerable.
- 6.2 Researchers should include the least vulnerable participants where it is consistent with their study aims.
 - 6.2.a Researchers must balance inclusion of vulnerable participants in research with the reduction of unnecessary risk and exploitation.
- 6.3 Researchers should provide all potentially vulnerable participants with appropriate support to help them make informed decisions about participating in a study.
- 6.4 Researchers must balance the rights of vulnerable individuals and groups and any potential benefits of their participation in research against any increased risk of harm.
- 6.5 Researchers must consider pursuing special protection of vulnerable participants' rights and welfare, while balancing this with respecting the autonomy of those individuals.

Diminished capacity to consent

For the purposes of these guidelines, there are three groups of people to consider when seeking informed consent:

- those who can give informed consent
- those who require assistance to give informed consent, and
- those who cannot give informed consent.

An unconscious person with no ability to communicate is an example of someone who cannot give informed consent, and marks the limit of the supported decision-making model.

- 6.6 It should be noted that almost any person, with the right support, is capable of providing informed consent. A person-centred, supported decision-making model should involve:
 - providing information to each potential participant on an individual, face-to-face basis
 - allowing adequate time for the process of obtaining informed consent

- delivering information in a form appropriate to the individual being consented, such as with tailored patient information sheets and consent forms which have been trialled with a group of people who are similar to potential study participants
- if the individual is unable to read or write, using verbal or other alternative methods of communication to convey information and record informed consent
- taking into account factors such as level of understanding, reading ability, and knowledge about research and research requirements
- involving members of the person's support network, while ensuring that potential participants experience no coercion in making their decision whether or not to take part in the research
- in the case of children with disabilities, providing assistance aligned to their identification as both a child and a disabled person
- if necessary, hiring a qualified person to conduct the supported decision-making process
- keeping a permanent record of the process, as evidence that information was provided in an appropriate manner and informed consent was obtained free from coercion.

The term 'capacity' refers to individuals' everyday ability 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. Capacity and competency are usually used interchangeably. Capacity refers to the ability to make decisions. Competence on the other hand refers to the ability to perform actions needed to put decisions into effect.

To have capacity/competence, participants must be able to understand the information relevant to their decision to participate in research, assess it, retain it, make a decision and communicate that decision.

The Code of Health and Disability Consumer Rights 1996 (the Code) identifies that every consumer of health and disability services must be presumed competent unless there are reasonable grounds for believing that they are not competent.³⁰

Where researchers have reasonable grounds for believing that participants do not have the capacity to consent to research, the research protocol must include a method for determining a person's capacity to consent. There is no all-purpose test for what will

³⁰ Right 7(2) of the Code of Health and Disability Services Consumers' Rights 1996.

be considered reasonable and the researcher will need to decide based on the particular facts.³¹

Diminished capacity may be due to a number of factors; for example, early dementia or other brain disease, brain trauma, drug intoxication, pain, distress, mental illness, disability, or reduced intellectual capacity. Research with participants who have diminished capacity is important, to address the health and disability needs of these groups.

- 6.7 Researchers should assume that every individual has the capacity to make an informed choice and give informed consent unless they have reasonable grounds for believing that this is not so.
- 6.8 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 ([Code of Health and Disability Services Consumers' Rights 1996](#)).
- 6.8.a In considering individuals' capacity to consent, researchers need to take into account the level of complexity of the study. They must provide information in an appropriate format (e.g. they should consider abbreviating or simplifying it, if necessary).
- 6.9 Capacity to provide informed consent can change over time, so researchers must consider the need to reassess a participant's capacity over the course of the study, and take into account any changes in capacity with regards to ongoing participation in the research.
- 6.10 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.

Supported decision-making

A supported decision-making regime comprises various support options that give primacy to people's will and preferences and respect human rights. It should provide protection for all rights, including those related to autonomy (the right to legal capacity, the right to equal recognition before the law, the right to choose where to live, etc) and rights related to freedom from abuse and ill-treatment (the right to life, the right to physical integrity, etc).

³¹ Skegg P and Paterson R Health Law in New Zealand p216

A supported decision-making regime should not overregulate the lives of persons with disabilities in a way that impacts their capacity ([United Nations Convention on the Rights of Persons with Disabilities 2006](#)).³²

All people risk being subject to ‘undue influence’; however, this risk may be exacerbated for those who rely on the support of others to make decisions. Safeguards for the exercise of people’s legal capacity must include protection against undue influence; however, such safeguards must respect people’s rights, will and preferences, including the right to take risks and to make mistakes.

- 6.11 Such a person may be able to exercise their right to consent to participate in research through supported decision-making.
 - 6.11.a Supported decision-making differs from substituted decision-making (consenting on behalf of another person) in that the latter approach does not involve the participant in the decision-making process. See section on [substituted decision-making](#).
 - 6.11.b In the context of supported decision making, the role of supporters (e.g. friends, family, whānau) is to facilitate an individual’s decision-making process. The potential participant should choose these supporters, and there should be no conflict of interest involved in the arrangement.
 - 6.11.c The term ‘support’ includes non-conventional methods of communication.
 - 6.11.d The level of support provided should reflect the level of complexity in a particular study and be sufficient to enable an individual to make a decision about whether to participate.
 - 6.11.e Supported decision-making results in an individual making their own informed choice.
- 6.12 For guidance on research involving an individual who has inadequate capacity to provide informed consent, even with appropriate support, see [Research with Adults who Cannot Provide Informed Consent](#)

Participants in a situation of power imbalance

Power imbalances do not inherently represent an ethical issue; indeed, all relationships are unequal in some way. Rather than focusing on inequalities themselves, researchers should focus on whether the inequalities are creating problems.

³² For guidance on determining capacity see Gilbert et al 2017.

Unequal power relationships may pose a risk in a study, depending on who is conducting the research and in what context. Such relationships include those between patients and doctors; people in residential care or supported accommodation and their caregivers; students and teachers; children or prisoners and custodians; refugees and government employees; members of the military and their superiors; committed mental health patients and health professionals; employees and employers; and in some cases Māori, Pacific Peoples, women, LGBTQI people, disabled people and people who are low-income and service providers within those communities who are receiving a service.

The power imbalance involved in these relationships may limit the extent to which consent to participate in research is truly voluntary; for example, potential participants may expect that they will get preferential treatment if they agree to participate, or may fear that they will be disadvantaged if they refuse.

6.13 Researchers must identify and take steps to minimise the risks of any unequal relationship that might restrict a person's freedom to choose to participate in research.

6.13.a Researchers should be aware that, in the context of research, it is often the case that researchers, rather than participants, hold the position of power.

6.14 When an individual declines to participate in or decides to withdraw early from research, the decision should not result in any negative consequences, such as unfair discrimination, a lower level of care or dismissal from employment.

6.15 Researchers must consider the potential for a power imbalance to influence their study results.

6.15.a For example, individuals in an unequal power relationship may be unwilling to answer sensitive study questions (such as questions about sexual or illegal activity) honestly.

6.15.b Similarly, they may over-report benefits because they want to please the researcher by providing the answers they believe the researcher wants to hear.

6.16 Researchers should consider whether hierarchical relationships may compromise a participant's privacy outside the study, and mitigate this risk.

6.16.a For example, research in a workplace may reveal the personal medical information of an employee participant to an employer researcher.

- 6.16.b Researchers should be aware of the extreme difficulty of protecting participant confidentiality when undertaking research in environments that intrinsically lack privacy, such as prisons, rest homes, hospitals and workplaces.

Managing unequal power relationships

Participants in imbalanced power relationships may be vulnerable to being ‘over-researched’ (that is, participating in research to an extent that becomes fatiguing or unethical) where researchers have relatively easy access to them as research populations. People in this position should not bear an unfair share of the burden of participating in research; nor should they be excluded from its benefits.

- 6.17 Researchers should take account of vulnerabilities arising from unequal power relationships in deciding whether to seek out members of certain populations as research participants.
- 6.18 Researchers must identify and take steps to minimise the risks of any unequal relationships.
- 6.18.a Suitable steps may include informing participants of their freedom to withdraw or decline to participate without adverse consequences, using an independent person to undertake the consent process and providing an independent advocate to participants to support their decision-making.

Research with children and young people

Children have equality of value and dignity with all other human beings. Research involving children and young people is important, to understand their unique physiologies and health and disability needs. However, researchers working in this area should acknowledge that additional protections are necessary for the safety and emotional and psychological security of participants.³³

Research involving children and young people raises particular ethical concerns, including:

- children and young people’s capacity to understand what the research involves
- in the case of adolescents, whether their consent alone is sufficient for them to participate
- the potential for undue influence from parents, peers, researchers or others

³³ For more guidance see <https://childethics.com> and Ministry of Health 1998.

- the potential conflicting values and interests of parents and children (NHMRC 2018).
- 6.19 Researchers should only conduct research with children if comparable research with adults could not adequately/appropriately answer the research question and the purpose of the research is to gain knowledge relevant to the health needs of children.
- 6.19.a Researchers must balance the benefits of inclusion of children and young people in health and disability research with the need to protect them against unnecessary harms.
- 6.20 Before undertaking research with children or young people, researchers must ensure that:
- if children from 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 are involved in the design, supervise and conduct the research
 - if a child participant 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 (Care of Children Act 2004)
 - they are aware of cultural considerations such as differing compositions of families and/or guardianship rights having been appointed to wider family members.
 - if consent is provided by a parent or guardian, the researcher still gets the child's assent (agreement) 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
 - through the research the child would receive therapy via the research for a condition for which there is no medically acceptable alternative.
 - if a child turns 16 during the course of a study, and if they have sufficient capacity the researcher seeks their consent to continue participation.
- 6.21 Only one parent or legal guardian is required to give consent on the child's behalf.³⁴

³⁴ Section 36(3)(a) Care of Children Act.

- 6.21.a However, if the research includes treatment which significantly differs from routine care³⁵, the researcher should consider the views of the other parent or other legal guardians.
- 6.21.b Guardians in exercising these responsibilities in relation to a child must act jointly (in particular by consulting wherever practicable with the aim of securing agreement) with any other guardians of the child. I.e. the consent of all guardians is not always required, even when the treatment is other than routine³⁶.
 - 6.21.b.1. However even with non-routine procedures, a practitioner should usually be able to rely on a guardian's assurance that any or all other guardians are in agreement. A researcher cannot be expected to always know how many guardians a child has or whether it would be practicable to consult with all of them in the circumstances.
- 6.21.c 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 seek consent from the child's new legal guardian as soon as practicable.

Consent and assent with children and young people

- 6.22 Researchers must respect the developing capacity of children and young people to be involved in decisions about participating in research. This is supported by the United Nations Convention on the Rights of the Child (UNCRC) which obliges health professionals to ensure children's voices are heard and given due weight in accordance with their level of maturity.
 - 6.22.a The capacity 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 of capacity, as levels vary from child to child.
 - 6.22.b A child or young person may be at different levels of capacity for different studies, depending on the type of research and its complexity.
 - 6.22.c Age alone has been shown to be an inaccurate marker of the level of children's competence.³⁷ Other internal factors which will impact on the

³⁵ Medical treatment for a child that is not routine in nature is considered for the purposes of the Care of Children Act to be "an important matter affecting the child. The Act considers that it is the responsibility of all guardians of a child to determine for or with the child decisions about important matters affecting the child.

³⁶ The general provisions of section 16 of the Act should not be read in a way which frustrates the effect of section 36 which indicates that legally effective consent may be given "by a guardian of the child."

³⁷ The Code of Rights does not specify any age for consent and makes a presumption that every consumer of health services is competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.

ability of a child to consent are prior experience of illness, level of independence, ethnicity, culture, and temperament.

- 6.22.d It is the responsibility of health professionals to impart information in a way age appropriate to the child. The time that a child has to digest and understand the information is another relevant factor (and may be a barrier to obtaining meaningful consent in an acute setting).
- 6.23 All competent children/young people must provide their own informed consent.
- 6.24 Participants aged 16 years or older who are competent should provide their own informed consent to participate in any medical research without health professionals needing to make further inquiries as to capacity.
- 6.24.a There may be circumstances where a 16 or 17-year-old is incapable of giving consent, whether because of disability, unconsciousness or other reason. In such a situation a guardian may be able to give a legally effective consent or if there is no guardian present in New Zealand, or a guardian cannot be found with reasonable diligence, consent may be given by a District Court judge or by the chief executive of the Ministry of Social Development, or services may be provided through [right 7\(4\) of the Code of Rights](#).
- 6.25 Different categories of maturity, and corresponding levels of competence may include:
- infants and very young children, who are unable to take part in discussion about research and its effects
 - young people, who are able to understand some relevant information and take part in limited discussion about the research, but are not competent to consent, although researchers should ask for their assent and respect their dissent
 - 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.
- 6.26 Research protocols (or institutional/departmental policies) must include a method for establishing the degree to which child participants are able to provide informed consent. To have adequate competence for this, the child must have sufficient understanding and maturity to adequately comprehend the proposed treatment or research participation and its potential consequences.
- 6.26.a Consent and assent are dynamic, continuous processes; researchers should check throughout the study to ensure they are maintained. If during a study a child participant develops the capacity to give consent,

the researcher must obtain their consent, which will replace their parents' consent on their behalf.

- 6.27 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, appropriate to the study's level of risk and the nature of the children's involvement. Illustrations may be helpful.
 - 6.27.a Researchers should engage young children with limited cognitive capacity, discussing the research and its likely outcomes at their level.
- 6.28 Researchers should keep research data on child participants for at least 10 years after the child has reached the age of 16 years.
 - 6.28.a Children should be offered the choice 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.
- 6.29 Researchers need to undertake good ethical practice and pay particular attention to ethical issues concerning children or young people if study participation involves the disclosure of sensitive information, such as sexual activity, drug use or abuse.
- 6.30 Researchers should consider making special provisions for protecting children's privacy, to ensure children provide accurate information, so they do not feel a need to lie to please their parents.

Researcher vulnerability

Researchers can also experience vulnerability. The process of collecting data or undertaking field work can be a stressful exercise for a researcher, particularly if the research involves illness or trauma. Researchers may bear witness to participants' experiences involving intense suffering, trauma, loss or other experiences that may cause an affective response in the researcher. Along with emotional risks, there can be physical risks to researchers: for example, threats or abuse.

Challenges cited by researchers conducting qualitative research include issues relating to use of researcher self-disclosure, feelings of guilt and vulnerability, the difficulty of listening to untold stories and exhaustion (Dickson-Swift et al. 2007).

- 6.31 Researchers should ensure they have adequate support to counteract the effects of vulnerability they may experience when conducting research.

7 Informed consent

Introduction

Informed consent is a dynamic process that begins with a 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.

Researchers have a duty to provide participants with information about the research they are being asked to participate in, potential risks and benefits, as well as the opportunity to ask questions and give their free and informed consent to participate in research, or to decline to do so.

In the context of research in New Zealand, the concept of mana tangata (personal autonomy) refers to a person's right to participate in research and their right to be appropriately informed of risks of harm to themselves or their collective. Through clearly explaining the requirements for informed consent researchers must demonstrate respect for the mana of participants.

Informed consent contributes to a number of ethically important concepts, such as transparency, supporting individual autonomy, protecting participants' welfare, promoting trust, satisfying regulatory requirements and promoting integrity in research.

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.

Suitable processes for obtaining consent

Requiring the consent 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. Researchers must consider the setting and timeliness of the consent process.

- 7.1 Researchers must seek and obtain the informed consent of individual participants before those participants begin to be involved in research, except in the circumstances outlined in [Research with Adults who Cannot Provide Informed Consent](#).

- 7.1.a Informed consent must be in writing if a patient is to participate in any research involving a healthcare procedure where informed consent is required.³⁸
- 7.2 Researchers should document participants' consent.
 - 7.2.a Where participants give consent in a form that is not written, researchers must record it in some other manner (e.g. through audio, video or electronic evidence, or a written note in the file).
 - 7.2.b In some cases, consent can be demonstrated by a participant's actions; for example, returning a completed questionnaire may be considered implied consent.
- 7.3 The study protocol must detail the researchers' process for obtaining consent, or their reasons for not seeking it, along with an ethical justification.
- 7.4 Researchers must give potential participants sufficient time and support to consider whether to participate in the study, as appropriate to the context of the study.
 - 7.4.a Researchers should consider the circumstances of potential participants during consent discussions. Potential participants have a right to support throughout this process; acknowledging this right is particularly relevant in stressful situations.
- 7.5 Unless an ethics committee has granted a [waiver of consent](#), or the study does not seek consent due to the [research population](#), researchers must seek consent before their study procedures begin, including consent for study-specific personal data collection and any additional diagnostic testing necessary for eligibility screening.
 - 7.5.a Researchers may review clinical notes and previously completed standard-of-care diagnostic tests prior to obtaining consent for eligibility screening (eg, a diagnostic biopsy or CT scan in the case of lymphoma).
- 7.6 If participants face barriers, including language barriers, it may be necessary for a researcher to seek their consent with help from an intermediary, such as an interpreter or advocate ([Code of Health and Disability Services Consumers' Rights 1996](#)). If a participant is unable to read, an impartial witness (a person, who is independent of the research, who cannot be unfairly influenced by people involved with the research) should be present during the entire informed consent discussion.

³⁸ Right 7 (6)(a) of the Code of Health and Disability Services Consumers' Rights 1996.

- 7.6.a In this situation, by signing the consent form, the intermediary or 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.
- 7.6.b Involving intermediaries may raise confidentiality issues. Researchers should discuss with participants whether family members are appropriate intermediaries; if the potential participant indicates that a family member does not have their interests in mind, researchers should consider finding someone impartial.
- 7.7 Researchers must give potential participants adequate time and opportunity to absorb the information provided, ask questions, and finally consider whether they will participate.
 - 7.7.a The amount of time needed for this first phase of the consent process will depend primarily on the needs of the participant, but may take into account such factors as the risk magnitude and probability of harms, the complexity of the information provided and the setting in which the information is given.
- 7.8 Participants may be faced with the necessity of 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, for example whether it is a high stress situation, and consider ways to reduce the risk of undermining the informed consent process.
 - 7.8.a For example, it may be appropriate for researchers to undertake the consent processes for the primary study and any optional components at a different times, as well as identifying **conflicts of interest** and avoiding **therapeutic misconceptions**.

Consent as a dynamic process

- 7.9 Researchers must notify participants of any substantial changes during the study that may affect them. Where researchers amend a study so that it substantially changes from what participants originally agreed to, they must seek participants' consent to continue to take part.
 - 7.9.a A determination as to whether a change is substantial and whether there is a corresponding need to obtain new consent is based on the context and circumstances of the study.

- 7.9.b Where researchers seek new consent, the information they provide participants should be new, and relevant to the participant's original consent. Its importance should be directly related to the participant's willingness to continue their participation (Dal-Ré et al 2008). In this case, the new information given to participants should be consistent with what a reasonable person, in that person's circumstances, would expect to receive to make a decision about continued participation
- 7.10 If a study requires several interactions between the participant and the researcher over time, or if the participant may be considered momentarily vulnerable for any reason, the researcher should ensure at appropriate points that the participant's consent is ongoing.
- 7.11 Researchers must use information and tissue collected about or from research participants only in the specific project to which the participant has consented.
- 7.12 If, at the time of obtaining 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 consent for data use in that context.
- 7.13 Participants have the right to withdraw at any point in a study without experiencing disadvantage.³⁹

Consent must be voluntary

Voluntariness is threatened by conflicts of interest and sources of vulnerability. See [Research Conduct](#) for information on management of conflicts of interest, and ethical management of vulnerability, which covers participants who may be more likely to experience undue influence on the voluntary nature of their decision to participate.

³⁹ See Right 7(7) of the [Code of Health and Disability Services Consumers' Rights 1996](#), which provides: 'Every consumer has the right to refuse services and to withdraw consent to services'.

- 7.14 Participants' consent to participate in research must be voluntary.
 - 7.14.a 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.
 - 7.14.b 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.

Consent must be informed

Effective communication is an essential feature of informed consent. The process of obtaining informed consent involves balancing potential participants' right to be fully informed against not overburdening them with information that reduces their ability to provide effective informed consent.

- 7.15 Participants must receive the information that a reasonable consumer, in that consumer's circumstances, would need to make an informed choice or give informed consent prior to their decision to participate in research.⁴⁰
- 7.16 Researchers must communicate relevant information in a form, language and manner that enables participants to understand the information provided, in an environment that enables both the participant and the researcher to communicate openly, honestly and effectively. Where necessary and reasonably practicable, this includes the right to a competent interpreter.⁴¹
- 7.17 Researchers must provide information in a form, language and manner that participants can understand. Information provided to participants, and any discussion of it, should be appropriate to the individual, taking into account their health literacy and their cultural and language background.
- 7.18 The person obtaining informed consent must be knowledgeable about the research and capable of answering questions from potential participants.
 - 7.18.a Participants must have the opportunity to ask questions and receive honest and accurate answers before or during the research ([Code of Health and Disability Services Consumers' Rights 1996](#)). Researchers must make every effort to address those questions in a timely and comprehensive manner.

⁴⁰ Right 6 (2) Code of Health and Disability Services Consumers' Rights 1996.

⁴¹ Right 5(1) of the Code of Health and Disability Services Consumers' Rights 1996.

Table 7-1 – Key elements to informed consent

| Study participation | Relevant information |
|--|--|
| <p>Nature of the study</p> <ul style="list-style-type: none"> • The purpose of the research, including its expected contribution to knowledge • The features of the 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 ethics reference number • Why the person may be suitable for the study • Why the person may not be suitable for the study | <p>Participants' rights, including:</p> <ul style="list-style-type: none"> • 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 participants, including the confidentiality of data in which participants 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 • How payments or other forms of reimbursement, if any, will be provided in recognition of participation |
| <p>Any harms, including foreseeable side effects, pain and discomforts, which:</p> <ul style="list-style-type: none"> • Describe the nature of harms for particular types of participants (e.g. women of childbearing age) • Express the likelihood of risk of harm as an event frequency (e.g. one in ten) • Define the severity of potential harm in terms of the damage that it would cause (e.g. discomfort, pain, trauma) • Communicate any risks of harm that may exist for a participant's family, whānau, hapū or iwi | <p>Information about the use of participants' tissue, which covers:</p> <ul style="list-style-type: none"> • How and where 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 methods for protecting their privacy and confidentiality • Whether 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 will 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 the outcomes of the research involving their tissue; how this will be managed; and who, if anyone, will benefit from such an application • Whether they may be able to have left-over tissue samples returned to them and whether the tissue can be disposed of, with a reassurance that researchers will record their wishes about the method of disposal at the start of the research and take those wishes into account at the time of disposal. |

Key elements to informed consent – continued

| Study participation | Relevant information |
|---|---|
| <p>What participation in the study will mean for participants, including:</p> <ul style="list-style-type: none"> • What will be done in the study in addition to usual health care or disability services (including dosing details, if applicable) • How participation will differ from non-participation • The time involved in participation • Any inconveniences likely to result from study participation, such as time off work • The nature, purpose and expected number of any extra tests to be performed during the study | <p>Information about:</p> <ul style="list-style-type: none"> • 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 (identifiable, re-identifiable or non-identifiable) in which the data will be accessed, used and stored during the life cycle of the research data • 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) of this on participants' rights • Whether participants may be able to withdraw their data, including the date up to which they can withdraw it • Procedures for withdrawing their data • Whether their data will be destroyed, and the procedures for destroying data |
| <p>Suitable contact details, including for:</p> <ul style="list-style-type: none"> • The researchers • A suitable cultural support person • An independent advocacy service (e.g. the Health and Disability Commissioner) • The ethics committee that has approved the study | <p>Researcher information</p> <ul style="list-style-type: none"> • 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 <p>Findings</p> <ul style="list-style-type: none"> • What findings could be identified from the study testing, and how any findings that are relevant to the health of participants will be communicated to participants |
| <p>Possible benefits of research participation</p> <ul style="list-style-type: none"> • For individual participants, whānau communities, hapū or iwi; and society at large; or any contributions it could have to scientific knowledge <p>Researchers' responsibility</p> <ul style="list-style-type: none"> • Extent of the researchers' responsibility to provide care for participants' health needs during and after the research, who will pay for costs associated with such care and the relationship between the participant's usual health care provider and the research team | <p>Information about what will happen after the study, including:</p> <ul style="list-style-type: none"> • 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 participants) • How researchers will communicate the research findings to participants and communities, and the expected timeframe for this • How the researchers will disseminate research results publicly, and whether published results will identify participants directly or indirectly • How the researchers will communicate the results of tests to participants, including incidental findings • Whether and how the research findings will be translated into health care |

- 7.19 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.
- 7.19.a Researchers should develop study information with potential participant input, to ensure it is appropriate and relevant.
- 7.19.b Information provided to participants should be proportional to the risk associated with study participation and appropriate to participants' circumstances. As a general rule, the greater 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.
- 7.19.c In some research that involves an intervention, participants may overestimate the likelihood or degree of benefit of the intervention (this is called 'therapeutic mis-estimation'), overlook the implications of study participation, or mistake research procedures for therapeutic ones (this is called 'therapeutic mis-conception'). Researchers should make particular efforts to obtain a valid informed consent by avoiding these effects.
- 7.19.d Researchers should also consider their own bias towards the study benefits. It is important that they recognise any such bias, and ensure they are providing accurate information; for example, by seeking input from other researchers in the field who are not directly involved in the study.

Table 7-1 includes a list of key elements of informed consent. They will not be relevant for all studies, and depending on the complexity and risk of the study, may be described in detail or briefly. Ethically, a balance must be struck between amount of information and the burden of information⁴². Researchers should provide participants with information, as relevant for the particular study, taking into account proportionality of information in relation to both the potential harms and benefits of the research and the type (or complexity) of the study.

⁴² Right 6 of the Code of Rights sets out the legal requirements for informed consent. Right to be fully informed

- (1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including:
 - (a) an explanation of his or her condition; and
 - (b) an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
 - (c) advice of the estimated time within which the services will be provided; and
 - (d) notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and
 - (e) any other information required by legal, professional, ethical, and other relevant standards; and
 - (f) the results of tests; and
 - (g) the results of procedures.
- (2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

Modifying the consent process

Sometimes, because of a study's design or the characteristics of the research population being studied, it is necessary for a researcher 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.

7.20 Any modification to informed consent procedures requires approval from an ethics committee.

7.20.a Examples are withholding information and deception, abbreviated consent, integrated consent, opt-out, health data or tissue waivers and research with adults who cannot provide informed consent.

7.21 When seeking approval for a modification to informed consent procedures, researchers must explain to an ethics committee how traditional consent (a written information sheet and consent form) would impact on the study in terms of its design or the research population, and consider and explain to what degree proposed alternatives affect participants' rights.

7.21.a These Standards aim to provide flexibility with respect to the ethical justifications made in modifying the consent process. Consent processes must still meet the [Code of Health and Disability Services Consumers' Rights 1996](#).

Electronic consent

Electronic procedures for consent, either online or in other digital formats, are increasingly replacing printed copies of participant information sheets and consent forms. Electronic consent forms can provide many advantages over handwritten equivalents, including customisability, fewer mistakes on forms, greater clarity on the purpose of the study and alternatives to participation, more flexibility as to adjusting or translating the form into other languages, increased availability of tools to assist comprehension, and flexibility as to where participants can complete the form. However, for disadvantaged groups with little or no disposable income to access and use electronic devices, electronic consent can be a barrier for participation in research.

7.22 Electronic consent forms must contain the same elements of informed consent as a paper equivalent, in a language the participant can understand.

7.23 Interactive formats should be simple to navigate. Researchers should not use electronic methods if participants indicate a lack of comfort with electronic media.

- 7.24 Researchers should make paper-based processes available where an individual or a community does not have access to the internet or a device on which to complete the electronic consent process.
- 7.25 Electronic consent methods must entail a means to ensure that the participant himself or herself provided consent.
- 7.26 Researchers should ensure that they can verify which version of the information sheet and consent form the electronic signature applies to.
- 7.27 Information about a study does not have to be in writing, and can be provided to potential participants using electronic methods. In deciding whether to use electronic methods, researchers should pay special attention to the information needs of specific patient populations and individual participants.
- 7.28 Electronic consent forms must contain information that assists the patients in understanding information relevant to the trial; for example, by using hyperlinked glossary terms.
- 7.29 Electronic consent applications must be compliant with relevant data security standards.
- 7.30 When utilising electronic consent, interaction between researcher and participant should remain an integral part of the consent process.

Withholding information and deception

- 7.31 Participants must still consent to participate in the research overall.
- 7.32 Where deception and/or concealment are part of the research design, researchers 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 to do so.
 - 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 participants, the community and the researchers or research.

- 7.33 In limited circumstances, providing very specific information about the study to participants in advance of seeking their consent could prejudice the purposes of collecting data, which would compromise the scientific validity of the study (e.g. advising participants about which arm of a trial (for example placebo or active drug) 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.
- 7.34 In other cases, because a request for permission to withhold some information could jeopardise the validity of the research (e.g. because participants may modify their behaviour in response), the researchers cannot tell participants that they have withheld some information until the data has been collected. In this case, 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.
- 7.34.a In this case, before the study starts, researchers must consider how participants' withdrawal of their data could impact on the validity of the study.
- 7.35 Researchers may (as part of the research design) sometimes deliberately misinform participants in order to study certain 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.
- 7.36 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.
- 7.37 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

Increasingly, research is being conducted as part of service delivery. Health systems can aim to improve medical care at the same time as they deliver it, by integrating the delivery of medical services with clinical research. The traditional lengthy process of

informed consent for research participation can complicate the process of embedding research into routine clinical care, reducing the time clinicians are able to devote to ordinary clinical care.

To address this, in some circumstances, for example [comparative effectiveness research](#), researchers may be able to justify using an integrated consent process, in which consent to participate in research occurs as part of a clinical discussion. In this case, the usual clinical discussion about treatment includes explaining that participants will include some research elements, such as being randomly assigned to one of the clinical options, and that their health data will be collected and used for the purposes of research.

However practical this may be, and even in low-risk comparisons between existing standard of care, significant practical and ethical concerns with integrated consent remain, particularly with respect to patient rights and individual autonomy. 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 to research participation into a clinical discussion, they are likely to give information to participants that is substantially briefer, for practical reasons, than the information that would appear on a written participant information sheet. Notably, explicit statements about voluntariness and confidentiality tend to be less detailed. Such a discussion must clarify that the patient will still receive treatment if they choose not to participate in the research; the discussion must distinguish between consent to treatment and consent to participate in research.

7.38 In this situation, researchers must seek consent to treatment prior to seeking consent for research.

7.39 At a minimum, the process of 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 (including randomisation, the use of data and any additional research procedures) transparent, and distinguish it from treatment
- explain the risks, benefits and rationale of the research component, and ensure that the risks of the research are no more than minimal
- document the consent processes and the discussion with the patient, where separate written consent is not obtained (the [Code of Health and Disability Services Consumers' Rights 1996](#)),
- respect the preferences and values of potential participants.

- 7.40 It is imperative that clinicians obtaining informed consent are experienced in obtaining consent, and are able to clearly explain the separate clinical and research components to potential participants. They must be able to weigh reasons of practicality against potential impacts on patients' rights, including the implications of reducing transparency and limiting patients' freedom of choice about treatment options.

Abbreviated consent in the case of medical emergencies or acute pain

In some circumstances, researchers may be able to justify using an abbreviated consent process to enrol an individual if following a standard consent process could seriously compromise that individual's health. An abbreviated consent process involves giving potential participants the information a person in their position would expect to receive given the circumstances they are in. This may be briefer than the information they would provide in the standard consent process, outside of a medical emergency.

For example, certain types of medical emergency practice can be evaluated only when a particular medical emergency occurs that necessitates the practice. Features of this context are acute pain, limited time to treat and competing care demands.

- 7.41 Subject to all applicable legal and regulatory requirements, researchers should consider whether an abbreviated consent would be appropriate, in order to balance informed consent with minimising harm.
- 7.42 When a participant's circumstances become more stable, researchers should offer them full information about the study. They should also seek the participant's fully informed consent to continue to participate in the study and for their already collected data to be included in the study.
- 7.43 If the participant is unconscious or lacks capacity to understand the risks, methods and purposes of the study, see [Research without consent with adults who cannot provide informed consent](#).

Opt-out consent

The phrase 'opt-out consent' (sometimes called 'passive consent') refers to 'consent' in which potential participants inform the researcher only when they do not wish to participate.

- 7.44 Researchers must take care that this recruitment method does not cause harm by making individuals unwitting participants.

7.45 An opt-out approach to recruitment may be appropriate when opt-in consent is neither practical nor feasible. Researchers must be able to justify an opt-out approach by ensuring that:

- potential participants have received appropriate materials informing them about the recruitment and study
- potential 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
- potential 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
- researchers address privacy concerns for sensitive research
- 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.

A note on ethics and the law: opt-out consent feasibility

The use of this method of consent is very limited in New Zealand. This is because the opt-out or passive consent does not meet the legal requirements of prospective informed consent.⁴³

NEAC recognise that there is a tension between ethics and the legal framework for consent. This tension creates a legal barrier to some research that may otherwise meet ethical standards. NEAC are aware of the tension and support a review of the law in this area.

Waiver of consent for secondary re-use of identifiable health data

Gaining informed consent to use previously collected identifiable data (including data-linking) should always be the default starting point. Where researchers propose to use identifiable data without specific consent for a study or project (e.g. where data was

⁴³ Right 7(1) of the [Code of Health and Disability Services Consumers' Rights 1996](#) states that services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent.

collected for care, or the proposed data use is not consistent with the scope of the original research consent), they must:

- 7.46 Satisfy national data standards, local data governance requirements
- 7.47 Justify to an Ethics Committee that the nature, degree and likelihood of possible benefits (including to participant and/or individuals and the value of the research to the public) outweigh the nature, degree and likelihood of possible harms (including to any participant and/or individual, other individuals, whanau, hapu, iwi, Maori communities and any other groups or communities). In determining whether to grant a waiver of consent, local data governance or Ethics Committees may also have regard to the following factors:
 - 7.47.a There are scientific, practical, or ethical reasons why consent cannot be obtained.
 - 7.47.b Appropriate data [governance](#) plans are in place.
 - 7.47.c The researchers have identified whether consultation is required, and if required they have undertaken appropriate consultation with cultural or other relevant groups, and those consulted support the proposed use.
- 7.48 When considering a waiver, researchers should identify if there is any known or likely reason to expect that the participant and/or individual(s) would not have consented if they had been asked.
 - 7.48.a It should be understood that a waiver of consent is not a waiver of responsibility, e.g. should there be an actionable incidental finding then it should be disclosed to the participant and/or individual.⁴⁴

⁴⁴ Code of Health and Disability Services Consumers' Rights, Right 6.

Waiver of consent for secondary use (re-use) of human tissue

- 7.49 Researchers must get **informed consent** from the person from whom the tissue was or will be collected before they use it for research, unless;
- 7.49.a consent from a family member has been provided in the case of a person being deceased or
- 7.49.b a **waiver** of consent is approved by an ethics committee.
- 7.50 Gaining informed consent to use tissue in research should always be the default starting point. Where researchers propose to use tissue without specific consent for research (e.g. where tissue was collected for clinical investigation, or the proposed 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.
- 7.51 Researchers should carefully consider whether they should undertake robust, active and ongoing engagement with relevant communities and stakeholders to establish whether the proposed tissue use is acceptable.
- 7.51.a Any such **engagement** should be transparent and fair, done in good faith and be truthful, consistent with the concepts and practice of whakapono and whakataukī.
- 7.52 When seeking a waiver, researchers should identify if there is any known or likely reason to expect that the participant(s) would not have consented if they had been asked. For example, are there elements which would be upsetting to the people who the tissue belongs?” This is not something for researchers to prove beyond reasonable doubt, but the researcher needs to consider this aspect of use of tissue without consent.
- 7.53 When research involves using clinical samples, researchers’ use of tissue must not compromise the primary clinical reason for collecting the tissue.
- 7.54 Researchers must maintain participants’ privacy and confidentiality throughout the period during which they are using and storing the tissue and its associated data.

- 7.55 Researchers must consider the potential psychological, social and cultural significance of their use of tissue, and plan to minimise all research harms.
- 7.56 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
 - managing privacy and confidentiality
 - returning results appropriately and [managing incidental findings](#)
 - giving special consideration to the issues involved in exporting or importing tissue.

Consent for future use of health data and human tissue

Increasingly, re-use of data and tissue is planned at the time of seeking consent for a study.

Future use of data

Future use of data refers to new data being prospectively collected and is different from previously collected data being re-used (refer to [secondary data use](#)). Future use of data encompasses both specified or unspecified future analysis, and future analyses related or unrelated to the research area leading to original data collection.

- 7.57 Participant and/or individuals in prospective data collection, in which future use under this definition is planned, must be informed as to the scope and relatedness of the request for consent for future use.

7.57.a Examples of information that might be relevant are:

- the identifiability of the data to be collected
- participants' rights of withdrawal of consent and, in particular, the possibility that, where data is made non-identifiable, an 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 use of the data, whether that use is limited to an already fully defined study or extends to a number of wholly or partially undefined studies, and the intended goal of such use (in terms of whether it is only for basic or applied research or also for commercial purposes)
- the procedures for return of results, including incidental findings
- the rules of access to the data, and who will manage access
- how confidentiality and privacy is protected
- where applicable, potential commercial use and benefit sharing, intellectual property issues and the transfer of data to other institutions or countries

- the conditions and duration of storage of the data
- the ways in which the individual can contact the databank or registry custodian and remain informed about future uses of the data
- 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.

Consent for biobanking (future unspecified use of human tissue)

New Zealand individuals can give consent to their tissue being used for future unspecified research, provided that they have received sufficient information and options for consent through a process that is distinct from that involved in the main study (Ministry of Health 2007). Storage and future use is ethically justifiable through 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.

7.58 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
- state whether genetic testing may be carried out on the tissue
- explain to the potential donor why he or she is being approached for his or her tissue, and specifically what tissue they are seeking
- 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 (or part of it) 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 and note that, 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 their 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.

Research with adults who cannot provide informed consent

This section addresses the ethical issues that arise in research involving adult participants who cannot provide their own consent. Most people, with adequate support, can provide their own consent to participate in research. See the section on [supported decision making](#) for guidance on seeking consent where adults have variable degrees of competency but with support are considered able to provide their own informed consent. See [‘waivers’](#) for retrospective research without consent involving data or tissue that has already been collected. In some cases another person may be legally able to give consent on behalf of an adult who is not competent to consent (see [“Substituted decision making”](#)).

Informed consent is still the primary means of protecting patient autonomy but in exceptional cases NEAC considered the ethics of research in the absence of consent⁴⁵. In some studies, informed consent is not an option, because the people involved in the study cannot provide consent. However, given that medical treatment extends to those with impaired decision-making capacity, it is important that researchers do not exclude people from research just because they cannot consent to participate.⁴⁶ Where certain populations (eg, people in intensive care units, people with dementia, the severely disabled and those in emergency care) have been excluded from research because

⁴⁵ This is in line with the Declaration of Helsinki see <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

⁴⁶ Right 7(3) of the [Code of Health and Disability Services Consumers' Rights 1996](#) states that a person with diminished competence retains the right to make informed choices and give informed consent to the extent appropriate to their level of competence.

they are unable to give consent, care or treatment options for those populations may be less strongly evidence-based, because insufficient research evidence is available.

The risks and benefits of studies with participants who cannot consent may vary from extremely high to negligible (See [Categories of Risk](#)). At one extreme, where significant incapacity or death is almost certain, a new therapeutic measure may offer a person a reasonable chance for recovery, sustaining life or preventing serious and permanent deficits. In other situations, the potential benefits and risks may be equally great – one may not outweigh the other. For example, drugs given in an effort to save the lives of trauma victims might do so at the risk of preserving those lives in a persistent vegetative state. Lastly, the research may involve treatments that are in standard of care, where it is not known which one is better, or which one should be used for different situations, and the only research elements are randomisation between the standards of care and data collection (see [Comparative Effectiveness Research](#)).

Many studies involving participants who cannot consent may be almost without risk, yet yield information useful in the treatment of the participant (e.g. by monitoring certain physiological events by non-invasive means).

When considering the ethical justification for research that involves adults who cannot provide their own consent, researchers must balance ethical principles in each study, as well as in each individual case of enrolment.

General ethical standards

- 7.59 Before participants unable to consent can be involved in research, an ethics committee must be satisfied that the particular research question cannot be appropriately answered by conducting research in consenting populations.
- 7.60 Health and disability research with participants unable to consent must be connected or responsive to the health needs or priorities of the group that the participants represent.
 - 7.60.a Such research is only ethical when the purpose of the research is to advance knowledge about the condition causing the participant's impairment or its treatment or relevant services.
- 7.61 Researchers are responsible for demonstrating to an ethics committee how their research meets these standards, by detailing the potential risks to individuals and the potential benefits to individuals and to others.

- 7.61.a Researchers should compare potential benefits and risks with standard-of-care options currently available, or with not participating, and explain any additional risks or benefits of participation to an ethics committee.
- 7.62 Where the researcher is also the treatment provider there may be a real or perceived conflict of interest when enrolling participants without consent. In such cases, it may be appropriate for researchers to seek an independent view on whether a particular participant's enrolment in a study meets legal and ethical standards.
- 7.62.a In the medical context, this may involve obtaining an independent clinical assessment.
- 7.62.b The requirement to seek an independent view should generally be limited to studies that pose more than minimal risk.
- 7.63 If a research participant regains capacity to consent, or some capacity to be supported in a decision, as soon as reasonably practicable researchers must give that participant the opportunity to give or decline informed consent to continued participation in the research, and to the use of data or tissue about them that has already been collected.
- 7.64 Where potential participants are capable of verbally or physically dissenting or declining, to participate in research, researchers should seek and respect that decision.
- 7.65 When a study enrolls a participant without their consent, researchers must pay special attention and make extra efforts to minimise that person's pain, anxiety and related social harms in relation to the enrolment.
- 7.65.a This requirement applies especially in cases where participants may not be able to adequately communicate pain or discomfort due to their condition.
- 7.66 When conducting research with adults who cannot provide consent, particularly in emergency contexts where seeking the views of a person interested in that individual's welfare is not possible, the research protocol should include additional safeguards.
- 7.66.a Additional safeguards should be discussed with an ethics committee, and might include:
- additional scientific, medical or ethics committee consultation
 - procedures to identify prospective participants in advance, so that consent may be sought prior to the occurrence of incapacity
 - consultation with former and or prospective participants

- special monitoring procedures to be followed by data safety and monitoring boards (Canadian Institutes of Health Research et al. 2014).

Respecting and seeking views

Adults who cannot provide their own consent cannot protect their own interests or indicate their preferences. Accordingly:

- 7.67 Researchers should respect the views held by people interested in the potential participant's welfare on whether participation in the research is consistent with the informed choice the participant would make if her or she were competent.
- 7.68 Researchers should also take reasonable steps to consult person(s) interested in the potential participant's welfare about that participant's continued involvement in the research, particularly if the research protocol is amended after enrolment.
- 7.69 If such a person is not able to be consulted and an intervention must be conducted in acute circumstances (e.g. emergency research), the research may proceed without that consultation, but researchers should continue to make efforts to consult a person interested in the welfare of the participant to establish whether the participant should continue to participate.

Enrolling participants in research

- 7.70 To meet New Zealand legal requirements, in order to enrol participants into research without consent, enrolment must be in the best interests of the individual, and reasonable steps have to be taken to ascertain the views of the potential participant.⁴⁷
- 7.70.a Best interests is determined on an individual basis, and while such determinations do not take into account potential benefits for other people, best interests determinations do include consideration of direct benefits (e.g. improvement of medical condition) and indirect medical

⁴⁷ Right 7(4) of the [Code of Health and Disability Services Consumers' Rights 1996](#) outlines the steps that must be taken if a provider is to provide services (including health research carried out in respect of any person) without consent:

Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where

- It is in the best interests of the consumer; and
- Reasonable steps have been taken to ascertain the views of the consumer; and
- Either:
 - If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
 - If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.

benefits (increased monitoring) as well as non-medical factors (e.g. emotional and other benefits) to the person themselves.

7.70.b The best interests test requires a net benefit, where participating is more beneficial than not participating.

7.71 When taking reasonable steps to ascertain the views of the potential participant, either:

- the potential participant's views are ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the potential participant would make if he or she were competent; **or**
- the potential participant's views are not ascertained, and the provider takes into account the views of other suitable persons who are interested in the welfare of the potential participant and available to advise the provider.

Substituted decision-making

Substituted decision making is when a legally authorised person consents on behalf of another person. Under New Zealand law, the group of people who can give consent for another adult to participate in health research is smaller than often assumed, and for research that involves medical experimentation their powers are very limited.

Generally, unless an adult has a welfare guardian, or someone holds an enduring power of attorney in relation to that adult, there will be rarely, if ever, be any individual who can provide legally effective substituted decisions.

The High Court may be able to make an order for clinical measures that are in the patient's best interests and of direct benefit to the patient themselves, however there is currently no precedent for this in the context of research.

7.72 Researchers should check the relevant legislation to ensure their enrolment processes meet legal requirements.

Welfare guardians

The Protection of Personal and Property Rights Act 1988 (PPPRA) empowers a Family Court to appoint a "welfare guardian" for some incapacitated adults.

Section 18(1)(f) states that no welfare guardian can consent to a person, for whom they are acting as a welfare guardian, taking part in any medical experiment other than one to be conducted for the purpose of saving that person's life or of preventing serious

damage to that person's health. The term "medical experiment" is not defined in the PPPRA, and its meaning has not been considered by the New Zealand courts. Some health and disability research are unlikely to be considered medical experimentation.

However, section 18(1)(f) does not preclude a 'medical experiment' involving a patient being carried out other than for the purposes specified in the PPPRA. It simply prevents this being done based on a welfare guardians' consent. For example, a practitioner may believe that the best interests of the patient dictate that the patient receives a treatment that is experimental in nature and thereby use right 7(4) of the Code to justify this course of action. This could equally apply to research believed to be in the best interests of a patient.

Attorneys, under enduring powers of attorney

Enduring powers of attorney in relation to personal care and welfare come into force after the 'donor' (the individual conferring the power) becomes mentally incapable and at this point the 'attorney' (the individual given the power) has the power to make decisions about the donor's personal care and welfare. The legal framework for this process is outlined in part 9 of the PPPRA.

In terms of medical research, section 98(4) of the PPPRA means that an attorney cannot consent to a person, for whom they are acting as a attorney, taking part in any medical experiment other than one to be conducted for the purpose of saving that person's life or of preventing serious damage to that person's health.

As for welfare guardians (see above), a practitioner may be able to rely on right 7(4) where they believe that the participation in the research would promote and protect the patient's welfare and best interests.

7.73 Where there is a legally authorised person, and the research is not a medical experiment, a legally authorised person may consent on behalf of an adult if they are satisfied that participation would promote and protect the person's welfare and best interest.

7.74 Researchers should check the relevant legislation to ensure their enrolment processes meets legal requirements.

The legality of research with adults who cannot consent

The legality of undertaking research with adults who cannot consent involves significant gaps in application. This area of law is governed by a number of legislative instruments, together with the common law. See, for example:

- Rights 4(4), 6(1)(d), 7(1), 7(2), 7(4), 7(5) and 7(6) of the Code of Health and Disability Services Consumers' Rights 1996
- Section 32 of the Accident Compensation Act 2001
- Sections 61 and 61A of the Crimes Act 1961
- Sections 10 and 11 of the New Zealand Bill of Rights Act 1990
- Protection of Personal and Property Rights Act 1988
- Mental Health (Compulsory Assessment and Treatment) Act 1992
- Article 12 of the United Nations Convention on the Rights of Persons with Disabilities 2006.

The provisions in both the New Zealand Bill of Rights Act and the Code of Health and Disability Services Consumers' Rights arguably relate to a person being physically involved in the research. When considering the legality of research involving unconscious consumers it is therefore important to distinguish between research where individuals directly participate (such as that involving an innovative practice or a clinical trial) and research that uses information normally gathered during the course of the delivery of a currently recognised health care practice or treatment (such as the clinical evaluation of a particular treatment). If the latter is the case (the research does not involve any additional information gathering above what would normally be associated with a particular treatment), the research may be able to proceed if it is conducted in compliance with the Health Information Privacy Code 1994.

However as the terms "health research" and "disability research" are open to broad interpretation and are not defined in the law, it is unclear whether the requirements of the Code for the provision of information and written informed consent may also apply to collection of data for the purposes of research at the time of treatment, as opposed to where data is sought to be used retrospectively. See [waiver of consent for secondary use of health data](#).

7.75 Due to the complex legal environment, researchers should seek legal advice to ensure that their research in this area is conducted in line with New Zealand law.

A note on ethics and the law - risks, benefits and the two-step approach

The role of NEAC is to determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services. It must also ensure that any advice and guidelines it issues comply with the laws of New Zealand.

This requirement creates a tension, particularly in the case of research with participants who are unable to consent, in which area the law is complex. For guidance in navigating

this tension, NEAC recommends that researchers consult the Health and Disability Commission Code of Rights, which restrict research with this population to cases where participation is in the individual's best interest.

The National Ethics Advisory Committee will publicly consult on any changes to the ethical standards if there is a proposed change in the law.

NEAC support a two-step approach that requires the level of risk of the research and the potential benefits to the individual, to determine the acceptable benefits that enable ethical recruitment of participants who cannot provide their own consent:

- Where the research imposes only **minimal risk**, it should have the prospect of providing benefits to the participants **or** the group to which they belong.
- Where the research exposes participants to greater than minimal risk, it should have the prospect of benefit for the individual participant. 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.

8 Research

benefits and harms

Introduction

Research can generate benefits for individuals now and in the future. However, all research carries some risks of harm ('harms' are defined in these Standards as events or experiences that set back the interests of one or more individuals).

Different studies carry different levels of risk of harm. Risks of harm to research participants are ethically acceptable only if they are outweighed by potential benefits. 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 the risks. Including participants in the design of research is an important part of recognising the benefits. Striking the right balance between potential benefits and risks of harm requires paying attention to the context of the particular study. Some studies are exploratory, in which case the benefits and harms can be more difficult to anticipate.

Benefits are events or experiences that advance the interests of one or more individuals. Categories of prospective benefits include:

- direct benefit for the individual, such as improvement in health condition
- indirect benefit for the individual, such as feeling helpful, gaining access to medical care that may not be available outside of the study
- 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.

To justify any risks of harm to study participants, research must have social and scientific value: that is, the potential to generate knowledge and methods that can protect and promote the health, wellbeing and independence of individuals, the population and groups within that population. Researchers must minimise risks and ensure that any that remain are outweighed by the potential benefits. The level of risk that is acceptable is up to the potential participants to determine.

In the New Zealand context, researchers should especially consider risks and benefits for Māori: see 'Research and Māori'.

Identifying and assessing potential benefits and risks of harm

- 8.1 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.
- 8.2 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.
- 8.3 Researchers must minimise risks of harm.

Managing and minimising risks of harm

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.

- 8.4 To manage risks, researchers must ensure that:
 - participants clearly understand the risks of harm associated with the research, and
 - mechanisms are in place to adequately identify and manage harms that may occur at any time during the research, and the research protocol specifies these measures.
- 8.5 Researchers must continue to manage the risks of harm 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.
- 8.6 The research protocol should document the processes for minimising and managing risks of harm. See '[Monitoring studies](#)'.

Benefits of research

8.7 Researchers must consider potential benefits as part of their consideration of the value of the research. Table 8.1 presents a non-exhaustive list of potential research benefits.

Table 8.1 – Potential benefits for different parties involved in research

| Recipients of benefits | Potential benefits |
|------------------------|---|
| Participants | <ul style="list-style-type: none"> • Access to information • Knowledge about diagnosis, interventions or procedures • Opportunities to share experience and greater solidarity with others (Rennie et al. 2019) • 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 • Increased knowledge about their disease or condition (Rennie et al. 2019) • Acquisition of life skills • Positive behavioural change • Enhanced sense of purpose • Bolstered self-esteem |
| Māori | <ul style="list-style-type: none"> • Community development (e.g. health-promoting events) • Researcher development (e.g. qualifications and research experience) • Knowledge advancement (e.g. through research outputs, hui (meetings and seminars) and wānanga (workshops and teaching sessions)) • Development of mātauranga Māori (the knowledge, comprehension, or understanding of everything visible and invisible existing in the universe) |
| Society | <ul style="list-style-type: none"> • Knowledge advancement (e.g. through research outputs, hui and wānanga) • Inclusiveness and diversity within the research system |
| Researchers | <ul style="list-style-type: none"> • Status and reputation, mana • Qualifications (e.g. through research conducted for Masters and PhD theses) • Personal advancement, particularly enhanced publication records • Increasing networks • Broadened life experiences and skills |

- 8.8 Researchers must also consider the risks of harm to others, such as potential stigma and whakamā 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.
- 8.9 Table 8.2 presents a non-exhaustive list of harms research participants may suffer.

Table 8.2 – Potential harms for research participants

| Category | Potential harms |
|--------------------------------------|---|
| Physical harm | <ul style="list-style-type: none"> Injury, illness, pain, permanent disability, death |
| Psychological harm | <ul style="list-style-type: none"> Feelings of worthlessness, distress, guilt, anger or fear (e.g. through disclosing sensitive or embarrassing information or learning about a genetic possibility of developing a disease) |
| Disrespect or harm to dignity | <ul style="list-style-type: none"> Devaluation of personal worth, including being humiliated, manipulated or in other ways treated disrespectfully or unjustly |
| Social or cultural harm | <ul style="list-style-type: none"> Damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; findings of a previously unknown paternity status; loss of trust; harm to wairua or mana |
| Privacy harm | <ul style="list-style-type: none"> Identification or disclosure of private information |
| Economic harm | <ul style="list-style-type: none"> Direct or indirect cost, i.e. cost for treatment for physical or mental harm caused by participation in the trial, particularly where the trial is not covered by ACC, and loss of earning potential from physical or mental harm caused by participation in the trial. |
| Legal harm | <ul style="list-style-type: none"> Discovery of criminal conduct or prosecution for it |
| Data harms | <ul style="list-style-type: none"> Surveillance, inferential harm or social harm such as stigmatisation |
| Autonomy harm | <ul style="list-style-type: none"> Coercion, inducement, undue influence, loss of agency |

Categories of risk

Levels of risk are used to determine ethical oversight in health research, including whether ethical review is required, and, if so, at what level. Risk levels are also relevant when considering the complexity of study documents, or whether modifications to consent procedures are ethical. In assessing risk, it is crucial to distinguish between harms that may be caused by the research participation itself and harms that are not, but rather

may be caused by the life situation or characteristics of research participants.⁴⁸ Risks can also be generated for populations after the research has been completed, see Interpretation of Study Results.

8.10 Ethical oversight should be commensurate to risk. Table 8.3 describes risk categories.

Table 8.3 – Risk categories⁴⁹

| Category | Details |
|------------------------|--|
| Negligible risk | <ul style="list-style-type: none"> Negligible-risk research is research in which the only foreseeable risk is one of inconvenience and/or discomfort. For example, participants being asked for their views about a topic rather than personal information about them is generally considered low-risk research. Research in which the risk for participants is more serious than discomfort is not low risk (NHMRC 2018). Discomfort includes such things as minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview. Discomfort however should be distinguished from distress. For example, a participant may experience whakamā (embarrassment) or stigmatisation and become distressed, at which point the risk is no longer negligible. |
| Minimal-risk | <ul style="list-style-type: none"> Minimal-risk research is research in which the probability and magnitude of harms in research are not greater than the probability and magnitude of harms ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Different populations can experience dramatic differences in levels of risks posed by daily life or routine clinical examinations and testing. These differences stem from inequalities in health, wealth, social status or social determinants of health. Researchers must be careful not to conduct research in ways that permit participants or groups of participants from being exposed to greater risks in research merely because they have low socio-economic status, because they are members of disadvantaged groups or because their environment exposes them to greater risks in their daily lives (e.g. poor road safety). Researchers must be similarly vigilant about not permitting greater research risks in populations of patients who routinely undergo risky treatments or diagnostic procedures (e.g. cancer patients). Researchers must compare risks in research to risks that an average, normal, healthy individual experiences in daily life or during routine examination: when the risks of an activity are considered acceptable for the population in question, and the activity is relatively similar to participating in research, then researchers can consider the same level of risk acceptable in the research context. These comparisons typically imply that research risks are minimal when the risk of serious harm is very unlikely and the potential harms associated with more common adverse events are small (NHMRC 2018). |

⁴⁸ See guidance on risk-based monitoring published on the [website of the United States National Institute of Mental Health](#). For more information on categories of risk in general, see the *International Ethical Guidelines for Health-related Research Involving Humans* (CIOMS and WHO 2016).

⁴⁹ These risk categories can be used by QI activities.

- More than minimal risk**
- Greater-than-minimal research is research in which the probability and magnitude of harm anticipated in the research is of more than minimal risk, but not significantly greater.
 - Studies that fall under this category will vary in terms of the probability of harm occurring as a result of study participation. Researchers should undertake safety monitoring depending on their assessment of that probability, ensuring adequate surveillance and protections to identify adverse events promptly and to minimise harm.

Table 8.3 – Risk categories – continued

Examples of more than minimal risk research

- Departure from normal care**
- Something withheld from or done to a patient that deviates from normal health care constitutes more than minimal risk (for example, when extra blood samples or biopsies are taken).

- Use of stored samples**
- Use, collection or storage of human tissue without informed consent and use of stored samples for study purposes other than those for which they were originally collected constitutes a more than minimal risk activity.

Exceptions to this rule include

- Where participants have given informed consent to future unspecified use of human tissue.
- Where a statutory exception to the need to gain informed consent (as set out in the human tissue act 2008, section 20(f) or the code of rights, right 7(10)(c)) applies.
- Where stored samples are used by health professionals undertaking one or more of the following activities to assure or improve the quality of services:
 - a professionally recognised quality assurance programme (for example, pathologists re-reading specimens to check the accuracy of their own or a peer’s work)
 - an external audit of services
 - an external evaluation of services.
- The justification for this is that the use is related to the primary purpose of the sample collection. See the Code of Rights, Right 7(10).

- Secondary use of identifiable health information without consent**
- Investigator use of identifiable health information that was primarily collected for clinical care for a secondary purpose without consent constitutes a more than minimal risk activity.

Exceptions to this rule include:

- where the individual, or the individual’s representative where the person is unable to give consent, has consented to this use or disclosure
- where the purpose for which the information is used is directly related to the purpose in connection with which the information was obtained
- where the source of the information is a publicly available publication and that, in the circumstances of the case, it would not be unfair or unreasonable to use the information
- where the information is used for statistical purposes and will not be published in a form that could reasonably be expected to identify the individual concerned
- where the use of the information for that other purpose is necessary to prevent or lessen a serious threat to:
 - (i) public health or public safety; or
 - (ii) the life or health of the individual concerned or another individual;

- where it is either not desirable or not practicable to obtain authorisation from the individual concerned and the information:
 - (i) is required for the purpose of a professionally recognised accreditation of a health or disability service;
 - (ii) is required for a professionally recognised external quality assurance programme; or
 - (iii) is required for risk management assessment and the disclosure is solely to a person engaged by the agency for the purpose of assessing the agency's risk; and the information will not be published in a form which could reasonably be expected to identify any individual nor disclosed by the accreditation quality assurance or risk management organisation to third parties except as required by law

The justification for this is that the use is related to the primary purpose of the data collection, and in such settings only individuals bound by a professional or an employment obligation to preserve confidentiality should have access to identified or potentially identifiable information.

Significantly-greater-than-minimal-risk

Significantly-greater-than-minimal-risk research is research in which there is a probability of an event that is serious, prolonged and/or permanent occurring as a result of study participation, or there is significant uncertainty about the nature or likelihood of adverse events.

- In undertaking research involving significantly greater than minimal risk, researchers must ensure adequate protections for foreseeable adverse events.
- In this case, researchers must also ensure additional safeguards, where feasible and appropriate. These might include:
 - additional scientific, medical, cultural or ethics committee consultation
 - special monitoring procedures to be followed by data safety and monitoring boards (Canadian Institutes of Health Research et al. 2014).

The distribution of potential benefits and risks of harm

- 8.11 Having identified potential benefits and risks of harm, researchers must carefully assess the likelihood and potential severity of the risks of harm to individual participants and groups, in comparison with the potential benefits.
 - 8.11.a When doing so, researchers should consider whether to seek advice from others who have experience with the same methodology, population and research domain.
 - 8.11.b They should also consider participants' own perceptions of risks and benefits.
 - 8.11.c No mathematical formula or algorithm can precisely calculate an appropriate ratio of benefit to risk of harm (Rid, 2010). Therefore, the comparison process 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.

- 8.12 Researchers must demonstrate a good understanding of the context in which a study is to be conducted.
- 8.12.a The context is especially important when the research offers direct benefits to the participants, their families and whānau, or to particular communities 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 with limited treatment options may be willing to accept research risks (such as treatment side effects) that would be unacceptable to well people.
- 8.13 When research interventions or procedures offer no potential individual benefits to participants, researchers must minimise the risks and ensure they are appropriate in relation to the social and scientific value of the knowledge.
- 8.14 In assessing potential risks and benefits, researchers must consider the relevant choices, experience, perceptions, values and vulnerabilities of different populations of participants.
- 8.15 Researchers should consult communities when determining whether the potential benefits of a study are outweighed by the risks of harm, or whether the balance is appropriate.
- 8.15.a 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.
- 8.16 In assessing potential risks and benefits, researchers should ensure 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
 - 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 (e.g. 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 do not bear a disproportionate share of the risks of harm
 - individuals, communities or populations that are socially or economically disadvantaged or marginalised are not over-represented in or unfairly exposed to risks of harm, or denied access to benefits.
- 8.16.a In some cases, overrepresentation may be statistically justified. Similarly, sometimes a study within a narrow group is justified, and can serve

equity goals (e.g. research into subgroups of populations, where risks and benefits would not extend to whole populations).

- 8.17 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 the unequal distribution, rather than choosing them arbitrarily or conveniently.
- 8.18 When the potential benefits do not justify the risks of harm in a research proposal, the researchers must reconsider their research aims, the methods proposed to achieve those aims or both.

9 Research development and design

Introduction

For research to be ethical, it must be well designed, and the research question must have the potential to lead to improvements in health or wellbeing. Well-designed research is scientifically robust, and uses a research methodology that takes account of relevant cultural, social and economic factors.

The design of a research study is critical in determining whether the research achieves its proposed outcomes, benefiting participants and communities. Tika refers to what is right or good in any given situation. In this context, it relates to the validity of the research proposal.

Research design

- 9.1 Researchers must ensure that their study design is appropriate to answer the research question.
 - 9.1.a Only appropriately designed research will justify the risk of harm, any inconvenience associated with it and resources allocated to it. A 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.
 - 9.1.b Research that is methodologically sound will meet generally accepted requirements relating to the subject matter, the population under study, and the research method and analysis. Internal validity, reliability, generalisability and translatability of study methods and results may be important aspects of the study's scientific value.
 - 9.1.c In the case of international research, where a design has already been developed, New Zealand researchers should consider how they can adapt the local documentation for a New Zealand context.
- 9.2 Researchers must have the necessary skills and resources to undertake and design the research. Alternatively, if appropriate, a supervisor may take responsibility for this.

- 9.2.a Researchers conducting clinical trials should be trained in Good Clinical Practice.⁵⁰
- 9.3 One or more individuals with the appropriate disciplinary and cultural knowledge, skills and experience must review the research. Reviewers must be impartial to and independent of the research team.
 - 9.3.a Some types of research (e.g. cross-cultural research) should entail an ongoing process of consultation.

Co-design, co-production or participatory research designs

Participant engagement in the entire research or QI process, encompassing activities from question identification through research design, data collection and analysis to interpretation, can often translate into better outcomes. Participant engagement may occur within any or all of the above stages. Co-design, co-production⁵¹ or participatory research designs⁵² involve a mutually advantageous collaboration between researchers and participants who may also be the end-users of research discoveries.

The nature of such designs makes it difficult to specify the study interventions or QI measures, or the roles of participants, in advance. It is therefore difficult for researchers to gain informed participant consent (and ethics committee approval) up front, as they would for traditional designs. This is one of a number of distinct challenges this methodology raises for researchers (and ethics committees); another is power imbalances.

- 9.4 Researchers should ensure they allow adequate time for the ‘design’ phase with participants, prior to formal trial and evaluation.
- 9.5 Researchers should be able to justify why the co-design 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.
- 9.6 Researchers should also be able to define the potential benefits of power-sharing in terms of reducing inequalities and empowering vulnerable communities, and

⁵⁰ For more information see part 11 of the Guideline on the Regulation of Therapeutic Products in New Zealand: [Clinical Trials – Regulatory Approval and Good Clinical Practice Requirements](#).

⁵¹ Co-production – ‘citizens are not only consulted, but are part of the conception, design, steering, and management of services’ - Christian Bason *Leading public sector innovation: Co-creating for a better society*, Bristol, Policy Press, 2010 or see Wiewiora A, Keast R, Brown K. Opportunities and Challenges in Engaging Citizens in the Co-Production of Infrastructure-Based Public Services in Australia. *Public Management Review* 2016; 18:483–507.

⁵² Participatory research “besides the mere participation of co-researchers in the inquiry, participatory research involves a joint process of knowledge-production that leads to new insights on the part of both scientists and practitioners” - Bergold, Jarg & Thomas, Stefan (2012). *Participatory Research Methods: A Methodological Approach in Motion* [110 paragraphs]. *Forum Qualitative Sozialforschung / Forum: Qualitative Social Research*, 13 (1). Art. 30, <http://nbn-resolving.de/urn:nbn:de:0114-fqs1201302>.

should have a developed plan for managing the relationships between themselves and their participants in ways that are likely to achieve these benefits.

- 9.6.a Researchers will find it helpful to establish a cooperative relationship with the ethics committee responsible for safeguarding participants' safety and welfare, and to make staged applications⁵³.

Protocol

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.

- 9.7 Researchers must conduct their research according to a suitably detailed protocol.

- 9.7.a The level of detail the protocol contains should be commensurate to the risk of the activity.

- 9.8 Protocols must include all information that is relevant for the type of study. Unless not relevant to the study type, all research protocols should include:⁵⁴

- 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 the expected benefits and merit of the research, and how they outweigh the harms
- a summary of the proposed research
- a description of the ethical and regulatory aspects, including the ethical risks and considerations raised by the study, and how researchers propose to deal with them
- a description of consultation undertaken, and how researchers have incorporated feedback into the research design
- any partnership arrangements in place with whānau, hapū and iwi
- the study hypotheses or objectives
- the main outcome(s) of interest

⁵³ Staged applications involves returning to the ethics committee through each stage of the research process, as aspects of the study may not be known during the first review.

⁵⁴ For further information on developing and designing protocols, see:

- the [SPIRIT Group's website](#)
- [CIOMS and WHO 2016](#), which contains a complete list of items to include in a research protocol.
- the [Equator Network's website](#), which has useful templates and practical guides for different types of study.

- 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, with justifications
- criteria for terminating the study, if appropriate
- what data will be collected, stored and used, and how it will be collected, stored, used and kept private
- the number of participants required to achieve the study objectives, and how the researchers determined this, for example using statistical methods
- an analysis plan appropriate to the study design
- how the study results will be shared publicly and communicated to participants
- disposal of study data
- actual or potential conflicts of interest, and how researchers will manage them.

Research population

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 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.

9.9 Researchers should not exclude participants on the basis of their age, disability, sex, sexual orientation, gender, place of residence, 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.

9.9.a Inclusion and exclusion of participants affect the extent to which researchers can generalise their findings. Researchers should enrol participants who represent all those to whom the research findings may apply, thereby contributing to an equitable distribution of research benefits and burdens.

9.10 Researchers must collect ethnicity data, unless there is a valid justification why this is not necessary.

Research with women

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. Furthermore, these Standards recognise the importance of women leading and contributing to research about women. In all cases, but particularly where research concerns issues where women, primarily,

are victimised (such as sexual assault and domestic violence), researchers must be competent in their understanding of gender stereotypes and gender-based power structures within society, and sensitive to the impact of these factors on women's lives and wellbeing.

- 9.11 Researchers should not exclude potential participants on the grounds of sex or gender expect where this is necessary for the purposes of the research.
- 9.12 Researchers should not exclude women from research without sufficient justification, or simply because they are biologically capable of becoming pregnant.
- 9.13 Researchers must recruit a sufficient number of women so that results are generalisable, and so that they reliably account for gender differences in treatment, disease processes or basic biological processes.
- 9.14 Researchers should be aware of specific circumstances in which women could be **vulnerable** in research, including: research with sex workers, research on family violence, research with trafficked women, research concerning abortion and research with women from a cultural context in which it is customary for them to make decisions in conjunction with a spouse or male relative.
 - 9.14.a When women in such situations are potential participants in research, researchers must ensure that they freely give their informed consent and provide suitable mechanisms for obtaining this consent.

Pregnancy

Because pregnant and breastfeeding women have distinctive physiologies and health needs, research designed to build knowledge relevant to the health needs of pregnant and breastfeeding women is important. There is a substantial gap in the medical literature regarding safe and effective health interventions for pregnant women, this has a negative impact on the health and wellbeing of pregnant women, their foetuses and future children. This lack of knowledge is both harmful and unjust. Therefore, research relevant to pregnant women's health needs must be promoted (Van Der Graaf, Van der Zande, & Van Delden 2019).

- 9.15 Researchers must not routinely exclude pregnant or breastfeeding women from participating in research. Researchers must carefully consider the available data and identifying important gaps within it. Researchers must not consider pregnant women to be vulnerable simply because they are pregnant.

- 9.15.a All participants (including pregnant women) are eligible to participate in studies unless there is a clear scientific reason to exclude them
- 9.16 Pregnant women and their foetuses are often physiologically vulnerable. Therefore, research must be designed to minimise the risk of harm to pregnant women and their foetuses.
- 9.17 Researchers should carefully consider what risks of harm their study may pose to the foetus, including stress or pain in utero.
- 9.18 In research involving women who are pregnant, the wellbeing and care of the woman who is pregnant take precedence, and then the wellbeing and care of her foetus takes precedence over research considerations (NHMRC 2018).
- 9.19 Rather than automatically removing women from a study when they become pregnant, researchers must carefully consider whether it is safe for women in the specific circumstance to continue to participate, taking into account that there is a lack of research data for pregnant women, and recognising that women might want to stay in the study.
 - 9.19.a Researchers must request consent to follow-up until birth for women who become pregnant during a trial where there is any possibility participation could have had adverse effects on the foetus.

Ethnicity data collection

One important step in addressing inequalities and achieving health equity is to consistently collect good-quality ethnicity data. This can be a source of comparative data, and can influence the outcomes and recommendations of research. Ultimately, it can contribute to improving Māori health outcomes and reducing inequities.

New Zealand is recognised as a world leader in its ability to analyse health data by ethnicity.⁵⁵ Health research helps to track the growing diversity of the population, and to provide more detailed information for planning, funding and monitoring health services.

- 9.20 All researchers conducting health research in New Zealand must collect good-quality ethnicity data⁵⁶.

- 9.20.a The process of collecting and reporting ethnicity data in New Zealand has evolved significantly over time. New Ethnicity Data Protocols, released in

⁵⁵ The Ministry of Health, through the Health Information Standards Organisation (HISO), publishes standards for the New Zealand health and disability sector.

⁵⁶ Please note an additional legal requirement to obtain approval to use cervical screening ethnicity data under Part 4A of the Health Act and the Health (Cervical Screening (Kaitiaki)) Regulations 1995.

October 2017 (Ministry of Health 2017a), are a standard of the Health Information Standards Organisation that cover research.

- 9.20.b In some cases (e.g. small studies with specific population groups), it may not be necessary for researchers to collect ethnicity data. However, it is good practice to include ethnicity as a variable as part of any demographic data. See [Equal explanatory power](#) below.

Equal explanatory power

In the New Zealand context, 'equal explanatory power' refers to the power of research to generate findings and offer explanations that are specific to minority communities. An aim to achieve equal explanatory power is an aim to produce information to improve Māori health to at least the same depth and breadth as information to improve non-Māori health.

Typically, nationally representative population samples aimed for 15 percent Māori but often underachieved due to inappropriate and/or ineffective methods of encouraging Māori participation. Smaller Māori samples limit the robustness of the Māori data analyses and therefore the relevance of the conclusions and recommendations for Māori.

Achieving equal explanatory power will not be practical for all contexts, especially for interventional studies that typically have a limited number of participants. In such situations, researchers should be aware of potential statistical issues with subgroup analysis within prospective interventional clinical trials and must avoid erroneous or dangerous conclusions.

Equal explanatory power in both quantitative and qualitative research in New Zealand is important, to prevent research conclusions from contributing to increasing inequality.

- 9.21 Researchers must consider the degree to which equal explanatory power is relevant for their study or hypothesis.

- 9.21.a In quantitative research of the general population, such as population surveys, this consideration may involve oversampling Māori participants.

Exclusion criteria

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 when their inclusion may impact on scientific validity.

Overprotective attitudes or practices on the part of researchers can exclude members of some groups in society from participating in research. In many cases, if knowledge about the health experiences and needs of these groups is to advance, they need to participate in research in appropriate ways.

9.22 Researchers should give special consideration to including individuals from **all groups in society** in their research.

Researchers' skills and resources

9.23 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 the potential benefits of their study.

9.23.a Some procedures may only be performed by health practitioners under the Health Practitioners Competence Assurance (Restricted Activities) Order 2005.

9.24 Researchers must have adequate facilities, time and resources available to them, to conduct their study safely and in the intended timeframes.

9.24.a Appropriate skills and resources may include:

- being competent in the relevant 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, and the ability to take full responsibility for appropriate research design, conduct and analysis
- appreciating the research context and environment, including understanding different community and cultural views
- understanding the inequalities in the health and wellbeing of populations, in particular those experienced by Māori and Pacific peoples
- the ability and resources to monitor participants throughout the research
- knowing researchers' ethical responsibilities and demonstrating ethical principles
- the ability to suitably protect confidentiality and data
- appropriate skills and resources to deal with unexpected events that may affect participants or researchers

- a suitable research setting (e.g. with qualified staff and appropriate infrastructures for safe and ethical conduct)
- an appropriate budget to allow researchers to complete their study in a timely way
- appropriate indemnity cover
- the capacity to disseminate and communicate research findings.

Peer review

A peer review process should be commensurate with the type of proposal, the potential risk to participants and the location of the research. The type of peer review process used must be fit-for-purpose and justifiable. For example, peer review of a graduate student project carried out largely within a tertiary institution will differ from that of a multi-centre clinical trial. Researchers may seek opinions from one or more peers who are independent of the study; the extent of peer review, like its type, should be fit-for-purpose.

- 9.25 In order to determine scientific validity, the peer review process should specifically determine the following factors:

- **The relative merit of the research:** As a key consideration, peer reviewers should determine whether the proposed work is important, worthwhile and justifiable. The research should address a health issue that is important for health and/or society. The aims, research questions and hypotheses should build on and address gaps in existing knowledge.
 - **The design and methods:** Peer reviewers should review the quality of a study's design and methods to assess its robustness. This might cover study methodology, a description of sample recruitment and characteristics (including number, gender and ethnicity, where relevant) and proposed methods of data analysis.
 - **The feasibility of the research:** Peer reviewers should consider whether the overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project. They should determine whether the research has the likelihood, on balance, of improving scientific knowledge, concepts, technical capacity or methods in the research field, or of contributing to better treatments, services, health outcomes or preventive interventions. Peer reviewers should assess whether the research will be achievable within the specified timeframe, and whether the research team has the appropriate experience and expertise to undertake the research.
- 9.26 Peer review should address the validity and feasibility of the design, methods and analysis of the study. Additional specialist (e.g. statistical, economic, cultural or analytical) review may be required.
- 9.27 Peer review must include a consideration of cultural relevance and appropriateness.
- 9.28 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. It may be appropriate to involve more than one reviewer.
- 9.29 Reviewers must be sufficiently independent to be able to conduct their review of the study without bias.
- 9.30 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.
- 9.31 Reviewers should consider the ethical aspects of the study. Studies can be of satisfactory scientific quality, as judged by peer review, but still pose ethical concerns.

Core features of the peer review process

9.32 An appropriate process for ensuring scientific validity will have the following features:

- **Peer review delivers an informed opinion:** An effective peer review process provides perspectives from subject matter experts. It may be appropriate for researchers to seek informed perspectives from individuals in the same organisation as the researcher, as long as the requirements of freedom from bias, equity and fairness can be met. An appropriate peer is one who can deliver an informed opinion on some or all of a proposal. Peer reviewers will be knowledgeable about the topic and/or context for the research; have the appropriate expertise relative to the breadth and scope of research under review; and, as a result, will be well placed to make a statement as to whether the research has verifiable scientific merit.
- **Peer review delivers an objective opinion:** Peer reviewers are charged with delivering a balanced and considered analysis of the research. Generally, the success of the peer review process is determined by the extent to which these evaluations can be considered free of bias, equitable and fair. Objectivity can be compromised if peer reviewers have conflicts of interest, and so appropriate peer reviewers typically will not be materially connected to the researcher(s) in a way that might undermine objectivity, and be free from either positive or negative inducements.
- **A consensus opinion on scientific validity is formed:** An ethics committee needs to receive assurance that the peer review process has delivered support for the scientific validity of the proposed research. When a peer review process involves a range of experts, it needs to result in a consensus opinion about the quality of the research.
- **Intellectual capital in the research proposal is respected:** A peer reviewer is in a privileged position, through having access to the unexploited ideas and intellectual capital of the researcher. A peer review process should require that reviewers do not disclose the substance of any research proposal, unless they have explicit permission to do so.

10 Ethical features of studies

Introduction

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

Studies can also be either invasive or non-invasive, either low risk or high risk, either therapeutic or non-therapeutic, and either comparative or non-comparative. A study's features and design, and the context in which it is carried out, all factor into the ethical considerations that researchers must make.

Observational studies

In an observational study, in contrast to an interventional (or experimental) study, the researcher does not influence the assignment of any variable. Instead, the researcher observes and analyses natural relationships between variables and outcomes, and records them.

The prospective collection of data – such as from blood samples, imaging or questionnaires – does not change the status of a study from observational to interventional. Observational studies are not automatically of minimal risk; indeed, they may involve an invasive or high-risk means of collecting data from participants, and therefore pose a risk of privacy harm. Researchers must rigorously identify, gauge, **minimise and manage** such risks.

10.1 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.

Examples of observational research

Observational studies include case control studies, cohort studies, cross-sectional studies, case reports, case series and descriptive studies.

- **Case control studies** examine the relationship between an attribute and a disease by comparing people with and without the disease with respect to the presence of the attribute or level of exposure to it.
- **Cohort studies** examine the relationship between exposure to a factor or factors and the probability of the occurrence of a disease (or other outcome) by observing large numbers of people over a period of time and comparing incidence rates of the disease (or outcome) in relation to exposure levels. A cohort study may be a clinical cohort study (e.g. where a group of patients with a given disease is followed to examine their prognosis).
- **Cross-sectional studies** examine the relationship between diseases (or other health-related characteristics) and other variables of interest in a defined population at one point in time, by collecting health and other information concerning members of the population, through methods such as questionnaires or surveys.
- **Case reports** are reports of individual cases from health or disability services or research settings.
- **Case series** describe a set of cases of a disease (or similar problem). For example, a clinician may assemble a case series on a topic of interest, such as an unexpected adverse effect experienced by patients taking a particular medication.
- **Descriptive studies** examine the existing distribution of variables in populations (e.g. analyses of cancer registry data or emergency department data by person, place or time).

Qualitative research

Qualitative research is a type of observational research in which researchers collect text-based rather than numeric information by methods such as interviews, case studies, focus groups, ethnography or direct observation. This strategy is suited to studies that seek to understand the health or treatment experience of individuals or communities.

Mixed-methods research incorporates both qualitative and quantitative methods. An example is research involving a debriefing interview that takes place after an intervention, to learn of barriers or facilitators to implementation of the intervention.

- 10.2 Researchers must consider whether the nature and duration of the research interaction may have a significant effect on a participant within a qualitative study.
- 10.3 Qualitative research methods may involve discussion of sensitive topics, or reliving upsetting experiences. In such cases, researchers should make

participants aware of the nature of the methods beforehand, and develop a plan for managing any distress participants may experience.

- 10.4 A close relationship may develop between researcher and participant as a result of direct sharing of personal information over a prolonged period. This may result in researchers being more likely to step outside of the research role in their interactions with participants (e.g. to provide counselling support). Where this happens, researchers should make it clear to the participant involved that they are no longer acting in the capacity of a researcher.
- 10.5 Researchers should take care to only provide support if this is in line with their professional skills.
- 10.6 Researchers must take additional care to preserve confidentiality when they publish qualitative data, because of small sample sizes and potentially identifiable contextual information.
- 10.7 Where possible, researchers should provide transcripts of audio recordings to participants before they undertake analysis, so that participants may adjust potentially identifying or misleading content.

Intervention studies

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'.

Intervention studies generally present more risk of harm than observational studies, however not all intervention studies pose significantly greater than minimal risk, and researchers should take care to avoid automatic classification.

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 (e.g. 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).

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 intervention arms in a way that minimises the influence of confounding factors (variables that are independently associated with both the exposure and the outcome of interest, are not on the causal pathway between the exposure and the outcome, and can distort a true relationship between the exposure and the outcome or create a spurious association).

- 10.8 Studies must be scientifically sound in order to be ethical. Researchers must design and conduct randomised controlled trials in a way that minimises systematic error (bias).
- 10.8.a Researchers should pay close attention to the means of randomisation (random sequence generation and allocation concealment), blinding of participants and personnel, blinding of outcome assessment, complete outcome data, and avoidance of selective reporting.
- 10.9 Researchers should ensure that participants enrolled in therapeutic intervention studies have post-study access to the best-proven intervention, where such an intervention is available. If the best-proven intervention is not going to be available to participants once the study has completed, researchers must clearly explain this to participants prior to their consent to participate.
- 10.10 Studies comparing two or more interventions should meet the standard of equipoise; that is, the expert medical community should be genuinely uncertain as to the overall balance of risks and benefits between the interventions offered in the study.

Managing risks of harm in intervention studies

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 and harm from receiving a placebo. At a community level, potential harms include an inequitable burden on a community without a corresponding benefit. Sometimes the potential benefits of an intervention study accrue to one group of individuals while its harms are experienced by a different group.

- 10.11 All trials of interventions for clinical conditions must include data collection and reporting of adverse events.
- 10.12 Researchers should conduct initial tests of a new intervention under lower-risk study conditions before escalating to higher-risk conditions, even if the new intervention is likely to be more therapeutically beneficial for a higher-risk population.
 - 10.12.a This approach may not be clinically appropriate if a new intervention is not applicable to a lower-risk group.

Incremental testing in early-phase trials

The safest possible manner of refining and testing techniques in an intervention study is to escalate doses incrementally, throughout testing. This approach also helps researchers to minimise the prospect of catastrophic events that might harm participants and undermine confidence in the development of interventions.

- 10.13 Researchers should justify dose level, dose escalation and cohort size in relation to international best practice.
- 10.14 Researchers should use methods such as sentinel dosing⁵⁷ along with careful safety monitoring, to protect participants from unnecessary risks.

Access to an intervention after the study

- 10.15 Participants who benefit from a study intervention during a clinical trial should have ongoing access to the study intervention for as long as it is clinically beneficial.
 - 10.15.a If continued access is not available, researchers must inform participants of this prior to seeking their consent to participate.
- 10.16 Researchers must clearly explain to all participants the arrangements for access to interventions after the study, including any uncertainties about that access.
- 10.17 Sponsors and researchers should seek access to effective interventions for study and target populations after the study, in discussion with relevant authorities.

Equipoise

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, in a study that meets the standard, no one can establish in advance

⁵⁷ Where one person in a first cohort of participants receives a single dose of investigational product in advance of the full study cohort

which of the groups in a proposed study will be better off through participating in the research.

10.18 For any study comparing two or more interventions, researchers should design the study 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).

10.18.a However genuinely felt, an individual feeling of certainty or uncertainty is not enough to demonstrate the presence or absence of equipoise.

10.19 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 who are randomised to the treatment arm.

Controls

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 having the goal of isolating the clinical effects of an investigational intervention) or an active control (where the investigational intervention is compared with an established effective intervention).

10.20 Participants in the control group of an interventional trial should receive an established effective intervention if one exists, unless researchers can ethically justify a different approach. The choice of control must be appropriate for the participants and the study design.

10.21 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.

10.22 Researchers who propose to delay or withhold established effective interventions must provide compelling justification for doing so. They must fully inform participants of treatments available to them outside the study and explain how these differ from study participation.

The risks of a placebo control are typically very low (e.g. ingesting an inert substance), but occasionally can be considerable (e.g. undergoing a sham procedure such as surgical incision under general anaesthesia).

10.23 Researchers must consider and minimise risks associated with placebos. They may use a placebo as a control when:

- the study is non-therapeutic (i.e. 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.

10.24 Compelling scientific reasons for placebo controls may exist when a trial cannot distinguish effective from ineffective interventions without a placebo control (Millum and Grady 2013). Examples of ‘compelling scientific reasons’ include the following.

- clinical response to the established effective intervention is highly variable
- symptoms of the condition fluctuate widely
- the condition under study is known to have a high response to placebo
- the rate of spontaneous remission of the condition under study is high.

10.25 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’), either during or after the study. In this case researchers should actively monitor participants, and should establish a threshold beyond which the participant should be offered the active treatment.

Cross-over studies and wash-out periods

A cross-over study is a specialised type of randomised controlled study in which the order that treatments are given is randomised. There may be more than one active treatment period as well as a placebo period. All participants are exposed to each active or placebo intervention and thus act as their own control. This reduces interparticipant variability, so fewer participants are required, which brings cost and safety advantages. This design is often used in uncontrollably heterogeneous circumstances (e.g. drug-drug interaction studies, where baseline interpatient variability makes it difficult to see an

effect if done in different patients). Treatment periods are typically separated by a 'wash-out' interval to prevent a carryover effect from the previous intervention.

- 10.26 Researchers must apply cross-over designs judiciously, having regard to any enduring effects of the intervention(s) beyond each treatment period and the stability of the background disease.
- 10.26.a A fundamental assumption inherent within the cross-over design is that participant measures return to baseline before the start of each new treatment period. Cross-over design is therefore unsuited to the study of interventions that researchers expect to produce an enduring response. A wash-out interval between periods of treatment should be sufficient to allow the condition to return to baseline.
- 10.26.b A cross-over design is unsuitable where the activity of the background condition is unstable.
- 10.26.c A cross-over design is unsuited to studies where there is a reasonable expectation of a high dropout rate.

Equivalence or non-inferiority trials

Not all clinical trials are designed to test whether a new treatment is superior to existing therapies. An equivalence trial aims to demonstrate that the efficacy of a new treatment lies within predetermined upper and lower boundaries of a standard treatment, being neither better nor worse than the standard. A non-inferiority trial aims to demonstrate only that a new treatment is no worse than a standard treatment.

- 10.27 Equivalence and non-inferiority trials must use an active control that is a current proven effective treatment for the indication being studied.
- 10.27.a To fairly test the equivalence or non-inferiority of a new intervention, the active control to which it is being compared must be used in a dose, formulation and population matching the trials in which it was proven to be effective. The selected response measure should be sufficiently sensitive to detect the expected effects of the intervention and control.
- 10.28 When a researcher proposes an equivalence or non-inferiority design, there must be a potential non-efficacy advantage associated with the trial intervention.
- 10.28.a Non-efficacy advantages include a more favourable side-effect profile, a dosing regimen that enhances compliance, lower cost and the potential to broaden treatment options to people with an idiosyncratic reaction to the standard treatment.

Adaptive design trials

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 during the study, with or without formal statistical hypothesis testing. The adaptation process generally continues throughout the trial, following the trial protocol. Modifications may be to dosage, randomisation proportions, sample size, the intervention(s) undergoing trial and the patient selection criteria. Importantly, adaptation within the trial protocol is set before the trial begins, specifying the adaptation processes. In some cases, such as Bayesian adaptive trials, the adaptation is driven by the early analysis of interim results of the participants previously recruited. The algorithm determining allocation may be specified, but the actual adaptive process is not determined until trial begins

Platform trial is a broad term for a type of clinical trial with a single master protocol in which multiple treatments and/or disease types are evaluated simultaneously. 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.

In oncology, 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. Similar approaches can be used in other disease groups.

Adaptive trials using either Bayesian or standard frequentist statistical analysis 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.

There are questions about how the complex designs of certain adaptive trials meet the substantial evidence standard required for new drug approvals, for example. Adaptive trials can create ethical challenges involving 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 especially important in this kind of study design, and researchers need specific expertise to perform them well.

10.29 In advance of initiating an adaptive clinical study, researchers should:

- ensure that the protocol clearly describes the adaptive nature of the study
- craft an informed consent document that accurately reflects the study's risks, and describes the adaptive nature of the study in lay language
- describe potential planned adaptations and the circumstances under which protocol amendments will be submitted for review to the relevant ethics committee.

Cluster randomised trials

Cluster randomised trials (CRTs) involve randomly allocating groups of individuals or clusters such as communities, hospitals or medical practices to different interventions, either using randomisation or step-wedge design⁵⁸. They pose distinct ethical challenges for several reasons, including the following⁵⁹.

- 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.
- A study may target certain social groups or organisations as the units of allocation, and potentially vulnerable persons within clusters may be difficult to identify.

A note on ethics and the law: consent and cluster control trial design

Under New Zealand law, a CRT is considered research which a patient under the Code has a right to be fully informed about and for which consent must be in writing. Every consumer has the right to the information that a reasonable person in the circumstances would expect to receive, including notification of any proposed participation in teaching or research and including whether the research requires and has received ethical approval.⁶⁰

⁵⁸ In the context of a cluster randomised trial, the stepped-wedge design involves the collection of observations at a baseline period in which no clusters are exposed to the intervention. Following this, at regular intervals, or steps, a cluster (or group of clusters) is randomised to receive the intervention.

⁵⁹ For more information see The Ottawa Statement on the Ethical Design and Conduct of Cluster Randomised Trials <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3502500/>

⁶⁰ Code of Health and Disability Consumer Rights right 6(1)(d).

NEAC recognises that there is a tension between ethics and the legal framework for consent, as cluster randomised trials generally are not designed to seek consent. This tension creates a legal barrier to some research that may otherwise meet ethical standards. NEAC is aware of the tension and support a review of the law in this area.

Generally, wherever the treatment (medical or otherwise, including gathering additional information from tests) under the study protocol is different, or for a CRT where it could be different to what the person would have received if not participating in the study, then consent for the research is required⁶¹.

CRTs that do not involve provision of health services

10.30 In the case of cluster randomised studies that **do not** involve health research, (i.e. are not under the Code of Rights) individual consent to participate in the trial should not be required if gaining that consent is impracticable, and the potential benefits from the study outweigh the harms.

10.30.a An example of such a study might be one examining the effects of a media campaign to reduce adolescent tobacco use.

10.31 When a CRT involves a group or community whose interests are substantially affected by the CRT, researchers should consult with representatives of the group to inform the study design, conduct and reporting, and to obtain their agreement to the study.

10.32 As far as possible, and whenever appropriate, researchers should involve community representatives in the planning and conduct of studies, and give community members the opportunity to contribute to them (e.g. through submissions or public meetings).

10.32.a 'Community representatives' include all the intended recipients of experimental (or control) interventions (including environmental manipulations), and those from whom the researcher intends to collect or access personal health information.

10.33 Participants may be patients or health care workers, or both. For example, in CRTs that target interventions to health care workers (e.g. an alternative hand-washing protocol), researchers may use aggregate data from patients' records to judge the effectiveness of the intervention.

⁶¹ However as the terms "health research" and "disability research" are open to broad interpretation and are not defined in the law, it is unclear whether the requirements of the Code may also apply to enrolment in research that involves the collection and analysis of data even where the treatment is the same for all participants (as opposed to using data retrospectively where it was originally obtained during the usual course of health care).

- 10.33.a Research involving health care workers may involve a power imbalance (that between employer and employee or entailed by a hierarchy of employees). When their research involves this or a similar power imbalance, researchers must consider procedures that particularly safeguard all participants' privacy and freedom to consent.

CRTs that involve provision of health services

- 10.34 For cluster randomised trials that involve health or disability interventions (service provision), researchers must obtain written informed consent from all participants, or someone legally entitled to consent on their behalf.
- 10.34.a In such cases, [integrated consent](#) may facilitate recruitment for CRTs.
- 10.34.b In cases where participants are adults who are unable to provide informed consent, researchers should review the Standards outlined in [research with adults who cannot provide consent](#).

Epidemiological and public health research studies

Epidemiological and public health research studies often involve the 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 CRTs, stepped-wedge and quasi-experimental⁶² study designs involving groups, geographic areas, institutions or systems collectively rather than individually).

- 10.35 For interventional research conducted in the context of health care or public health, researchers should additionally determine⁶³:
- 10.35.a whether the project involves the systematic investigation of the safety, efficacy and/or effectiveness of an intervention;
- 10.35.b if the research involves exposure to an intervention for which the safety or efficacy, or both, is not well understood:
- 10.35.c whether it is likely or possible that the intervention will be of therapeutic benefit and

⁶² A quasi-experiment is an empirical interventional study used to estimate the causal impact of an intervention on target population without random assignment

⁶³ Adapted from the Australian National Statement on Ethical Conduct in Human Research (2007)

- 10.35.d whether there is a realistic possibility that the intervention being studied will be at least as beneficial overall as standard treatment, taking into account effectiveness, burden, costs and risks;
- 10.35.e where patient care is combined with intent to contribute to knowledge, that any risks of participation should be justified by potential benefits to which the participants attach significance. The prospect of benefit from research participation should not be exaggerated, either to justify to the reviewing body a higher risk than that involved in the participant's current treatment or to persuade a participant to accept that higher risk;
- 10.35.f whether the intervention or other research procedures are without likely benefit to participants. For such research to be ethically acceptable, any known or emerging risks to the participants must not be greater than the risks that would be associated with the health condition and its usual care.

Health system improvement research

The health sector has a critical role in conducting health services research and in translating research findings into policy and practice⁶⁴. It can encourage practitioners to take up new ideas by involving health professionals in research, evaluation, **quality improvement** and improved service delivery.

Research questions focus on what needs to be done to improve health system performance and how to influence policy to strengthen health systems, and frequently focus on 'hardware aspects' of healthcare, such as financing, information technology, service delivery, human resources and governance or 'software aspects' (norms, values and power relations) of health systems (*Pratt et al. 2017*). Importantly, they typically do not recruit patients or consumers directly, rather they are targeted at the population level, health system process level or health workforce level. Health systems research encompasses and overlaps with other types of research including comparative effectiveness research (CER), implementation research and activities (that may or may not be research) like quality improvement (QI).

The ethics of these areas of research are a new field and will require further work and frameworks to be developed.

⁶⁴ See <https://www.health.govt.nz/publication/new-zealand-health-research-strategy-2017-2027> for more information on New Zealand's Health Research Strategy

Comparative effectiveness research

Comparative effectiveness research (CER) compares established treatments (standards of care) or services when existing evidence is insufficient to determine which has the superior balance in terms of efficacy or safety. Such research aims to address variation in use of standards of care, or service delivery. It is often lower risk, and is integrated into routine delivery of care or support services and may require consideration of the dual role of service provider and researcher.

- 10.36 Researchers considering a 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 groups to whom the treatments should be applied.
- 10.37 Researchers must 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. Researchers should base decisions about criteria on a thorough analysis of expert views
 - introducing risk reduction strategies, such as increased monitoring, as part of the clinical trial itself
- 10.38 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. In certain circumstances, other approaches to consent described in these Standards such as [integrated consent](#) or the inclusion of participants unable to consent may be applicable.
 - 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.

Health services research⁶⁵

Health systems research has been defined as ‘a search for knowledge which contributes to health systems strengthening and our understanding of health systems (Pratt *et al.* 2017).’. Health services research examines healthcare at the organizational level (e.g. clinics and hospitals).

The standards below provide high level principles that should guide health services research.

- 10.39 Researchers must consider health services research impact on reducing health inequity, and avoid widening of health disparities (i.e. where incentives⁶⁶ are taken up differently by different groups)
- 10.40 Researchers must ensure health services research includes people experiencing **vulnerability**.
- 10.41 Researchers must carefully consider what a ‘standard of care’ is when conducting health services research that involves changing or implementing a new standard of care.
- 10.42 Researchers should conduct community engagement when designing health services research.
- 10.43 Researchers must consider and balance social and cultural **risks**, as well as medical risks of harm.
- 10.44 Researchers must consider collective risks when conducting population level health services research.
 - 10.44.a Examples are costs to healthcare systems, reputational damage to groups, lack of intervention sustainability.
- 10.45 Researchers should consider whether informed consent from individuals is required. This determination will be based on who the target of the intervention or object of study is.

⁶⁵ This section has been adapted from *Ethics of health policy and systems research: a scoping review of the literature 2017*.

⁶⁶ Incentives may be financial or reputational. See How Financial and Reputational Incentives Can Be Used to Improve Medical Care <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5338201/>

- 10.45.a For example, whether it is a system-level intervention, a healthcare worker intervention or an individual patient intervention. Other considerations are the level of risk for individuals.

Implementation research⁶⁷

Implementation research (IR) is growing in recognition as an important generator of practical knowledge that can be translated into health policy. IR increases understanding of how to improve access to health products and strategies that are already available and demonstrated to work, but which remain beyond the reach of many people who could benefit from them. It identifies practical problems faced by, for instance, disease control programmes, and seeks methods of improving access to health interventions which in turn lead to better health outcomes. It also addresses different aspects, such as social and contextual factors, implementation processes, and outcomes.

IR provides the link between theory and practice. For example, in case of a new vaccine for prevention of measles, traditional clinical trials will address safety and efficacy while IR seeks to answer questions of accessibility, acceptability, appropriateness, and feasibility in the communities where the vaccine is needed. However, IR is not always related to disease treatment or prevention, but may also focus on routine healthcare delivery, cost-effectiveness, policy, health education, and so on. It therefore draws flexibly on a variety of research approaches to address its diverse research questions.

This distinction between IR – which focuses on the application and practicalities of interventions – and biomedical and clinical research – which establishes evidence for use of these interventions – calls for a different application of Te Ara Tika and bioethical principles. The table below provides information on the ethical impact of these differences.

Table 10.1 – Ethical differences between clinical health research and implementation research

| Domain | Clinical research | Implementation research |
|-----------------------|-------------------|--|
| Research participants | Individuals | Institutions, communities, and individuals |

⁶⁷ This section has been developed from Gopichandran et al., Developing the ethics of implementation research in health. *Implementation Science*. URL: <https://implementationscience.biomedcentral.com/articles/10.1186/s13012-016-0527-y> (accessed 07/11/19).

| | | |
|---|---|--|
| Informed consent | Informed consent by competent individuals, assent and or consent by legally authorised representatives | Consent may be difficult to obtain in cluster randomised trial design. There may be a need for a two level consent—consent for randomisation from gatekeepers ⁶⁸ and consent for participation at the individual level. Sometimes individual consent may not be feasible. However, gatekeeper consent does not replace the need for individual consent. |
| Equipoise | Clinical equipoise | Clinical as well as contextual equipoise (genuine uncertainty that the implementation will work in a new context as well as whether the implementation package will work at all) |
| Pre-requisites | Understanding of disease pathophysiology Intervention aimed at disease-specific management | Identification of population health needs Understanding relative priority of need for intervention within local context Community engagement to understand community needs, ensure scalability, and sustainability |
| Research conditions | Generally controlled research environment | Real-life or pragmatic research environment |
| Research designs | Cross-sectional, case-control studies, Cohort studies, randomised clinical trials | Cluster randomised trials Pragmatic, mixed methods, effectiveness implementation hybrid designs, participatory action research, quasiexperimental design, realist review |
| Integration within health system | Often, there is no a priori plan for health system integration. Findings of clinical research go through IR before integration into health system | IR has a strong health system strengthening focus. It creates horizontal integration into the health system. There is an ethical imperative for health system integration |
| Predominant research disciplines | Physiology, genetics, biochemistry, and other basic sciences, epidemiology, clinical medicine | Anthropology, Economics, Epidemiology, Political science, Public health, Sociology |
| Control groups | In most epidemiological designs, control groups are required. But some phase 1 clinical trials and observational studies may not require control groups | Having a no intervention control group may not be acceptable. Alternative designs of quasi-experimental studies do not require a control group |
| Boundary between research and clinical care | This boundary is usually clear, but may be unclear in case of therapeutic misconception especially in cancer trials | Is often unclear, because the intervention is of proven efficacy |

⁶⁸ For instance, a GP may be a gatekeeper in the health context.

| Types of research question | Efficacy and safety of a therapeutic strategy in the individual | Operationalization of an intervention in local context Implementation of an intervention in local context prior to scale-up Policy analysis Health system functioning at multiple levels |
|-----------------------------|--|---|
| Anticipated outcomes | Well-defined hypothesis at the beginning of the clinical research. Expected outcomes clearly stated | Multifaceted holistic impact on health systems functioning with regard to intervention tested. Sometimes outcomes may be unexpected |
| Risks assumed by: | Mostly, the risks are for the study participants. However, families and communities may also be affected in specific contexts | Usually population level risks. Moreover, the people getting the benefits and people suffering the risks may be different. |
| Benefits accrued by: | Benefits accrue to the participants, the community. The research finding may be a common good | Individuals, communities, health system, institutions may benefit. The research findings may be common good. The people accruing benefits may be different from those who suffer risks |
| Generalisability | Generalisability is sometimes possible in multicentric and well sampled studies, however most studies are specific to the target populations. | Generalisability may be limited by contextual factors. However, findings may be generalisable to similar contexts |
| Social justice implications | Social justice is usually not a primary consideration. However, justice considerations are required in selection of research participants. Research on vulnerable participants is often contentious because of compromised autonomy and other logistics | Social justice considerations are primary. Working with vulnerable groups essential to understand implementation issues in these groups so that the intervention can reach them |

The ethical considerations required for IR can be further divided into the three phases of its research life-cycle: the planning phase, the implementation phase, and the post-research phase. While these phases bring their own ethical challenges, a core ethical imperative of IR as a whole remains the strengthening of the health system.

10.46 Strengthening the capacity to translate research findings into health policy is ethically important in implementation research and must be a component of all phases of the IR process.

Ethical considerations in the planning phase of implementation research

- 10.47 Researchers should engage with local health experts, communities, and stakeholders during the planning of IR.
 - 10.47.a Situational analysis is crucial in implementation research, and engagement and consultation will assist in meeting the ethical requirements of IR.
- 10.48 Implementation research must reflect high local need.
 - 10.48.a Engagement and analysis is essential in the planning stages of IR to determine if a health problem is indeed perceived to be a local priority.
- 10.49 The clinical or public health problem to be addressed by implementation research must be adequately identified. The epidemiology of the disease or health status must be understood, and the local situation analysed to identify accessibility of care.
 - 10.49.a In the case of new interventions or those adopted from other countries, local situational analysis is important to determine the differences and similarities between communities where the intervention has been successfully implemented and communities in which the intervention will be tested.
- 10.50 Implementation research must meet the situational or contextual equipoise standard; that is, to ethically justify implementation research there must be reasonable doubt as to whether a new and untested intervention(s) will work in a specific context.
 - 10.50.a This is related to the equipoise standard for clinical research, which requires it be in doubt whether an intervention is superior or inferior to what it is being compared with. See [equipoise](#).
- 10.51 Researchers must balance the risks and benefits of implementation research to both individuals and communities.
- 10.52 Data ownership should be fairly negotiated during the planning of implementation research. Transparent stakeholder engagement should establish appropriate ethical oversight of data, and plan for future access to research findings.
- 10.53 Implementation research should ensure commitment upfront to the sustainability of any interventions found to be effective.
 - 10.53.a If access to a proposed public health intervention cannot be ensured for a community after the IR, it may not be ethical to carry out such a research activity.

10.53.b Provision of interventions without a plan for sustainability could lead to harmful effects to the community, increased inequity, and loss of trust in the health system.

10.54 Researchers should consider the specific ethical issues raised by methods employed in undertaking IR.

10.54.a See table 10.2 for ethical issues relating to variable implementation research designs.⁶⁹

Table 10.2 – Ethical considerations relating to variable implementation research designs

| IR design | Features | Example | Ethical concerns |
|---|---|--|--|
| Cluster randomised trials (group randomised, placebo-based, community wide intervention trials) | Random allocation of groups or “clusters” to study arms and outcomes are measured in individual subjects and at community level | Randomization of clusters of obstetrics unit staff to education on hand washing or usual practice, measurement of rates of puerperal sepsis in women delivering at study clinics | Different units of intervention and outcomes measurement Consent before and after randomization, whom to consent? Choice of gatekeepers No opt-out option within cluster Risk: benefit balance Ethics of randomization to known intervention, equipoise, Identification of vulnerable groups |
| Effectiveness-implementation hybrid trials | Assess both effectiveness and implementation strategy simultaneously Identify intervention—implementation interactions | Evaluate impact of ITN on reduction of malaria and assess robustness of availability and uptake of ITNs in the community | The trade-off between the scientific rigor required for effectiveness assessment and the realistic contextual considerations required for implementation is an important ethical consideration |
| Mixed-methods research | Use of both qualitative and quantitative methods Understands various perspectives Rationales: “participant enrichment”, “instrument validity”, “implementation validity”, “meaning enhancement” | Integration of HIV and TB management in single clinics—patient experience (qualitative) and adherence (quantitative) | The trade-off between the scientific rigor required for quantitative methods and the realistic contextual considerations required for the qualitative component |
| Participatory action research | Research question, design, and data collection in a participative manner by the research participants “Bottom-up” approach | Peer support groups to improve adherence to ARV in HIV + subjects | There is a need for community engagement to ensure responsiveness, sustainability, and scalability |
| Pragmatic trials | Effects of intervention in routine practice Maximize variability of settings, practitioners, patients | Introduction of community health workers for home management of malaria | There may be concerns of standards of care and ancillary care, which in pragmatic conditions may be ethically debatable. |

⁶⁹ Gopichandran et al., 5.

| | | | |
|--------------------------|---|--|--|
| Quasi-experimental study | Real-life conditions With or without control group No randomization | Open label demonstration project of effectiveness of self-reported use of pre-exposure prophylaxis for HIV | There is a concern regarding scientific rigor of the research |
| Realist view | Analysis of how and why an intervention works in a context combining theory and empirical evidence. | Integration of traditional healers into home management of malaria strategies | Community engagement is of utmost importance to retain cultural and contextual sensitivity |

10.55 Implementation research must balance potential risks and benefits, and conduct diligent situational analysis to determine contextual risks and benefits.

10.55.a For example, in IR the community at large may benefit from a treatment which resulted in a side-effect for an individual who did not require that treatment. Alternatively, an intervention may be implemented in one group while the benefits accrue to a different group.

10.55.b Contextual risks may result from cultural or financial factors which bring risks of stigmatisation and/or discrimination in one setting where not present in another.

Ethical considerations in the implementation phase of implementation research

As explained in relation to randomised cluster trials, non-consensual research raises complex legal issues in the New Zealand context, where ethics committee are unable to provide prospective waivers of consent.

10.56 Implementation research may involve modifications to the traditional informed consent process depending on the design. Researchers should consult the Code of Health and Disability Service Consumers' Rights to consider whether the IR project meets informed consent requirements under New Zealand law.

10.56.a In IR the informed consent process can be difficult to operationalise at the individual level, and these activities often involve 'relational' rather than 'individual' autonomy, where participants are recruited into the research as groups or communities.

10.57 Where implementation research requires access to individual-level data, safeguards must be put in place to protect individuals' privacy.

10.57.a This is especially important when data is accessed without explicit consent. Risks to the individual's autonomy can be off-set by increased protection of data confidentiality.

- 10.57.b The most effective safeguard of privacy is the provision of data to IR projects in a de-identified form.
- 10.58 When deciding on the standard of care or prevention to be provided to a control group, researchers should consider its adequacy against the justice principle.
- 10.58.a For example, simply providing an existing standard of care which is obviously insufficient is unfair and ethically unacceptable. Alternatively, a standard of care which is not currently in use but agreed upon by public health experts and the community could be employed. Fairness should determine whether a local de facto or local de jure (respectively) standard acts as a control.
- 10.59 Implementation research should strengthen the health system in which it was conducted.
- 10.59.a For example, IR should identify any technologies or expertise required for post-intervention scale-up.
- 10.60 IR projects should focus on horizontal integration of public health interventions and avoid vertical program structures.⁷⁰
- 10.60.a Vertical structures can be disempowering to the health system through inefficient resource utilisation.
- 10.61 Implementation research should lead to strengthened research capacity of the local institution and individuals' capacity to conduct research in settings where such capacity is weak.
- 10.61.a This can range from creating a trained workforce of researchers to building capacity and infrastructure to allow independent conduct of IR in the future.

Ethical considerations in the post-research phase of implementation research

- 10.62 Given the important public health impact and objectives of implementation research, findings should be widely disseminated, including feedback to communities and stakeholders who participated in the research.
- 10.63 Communities and individuals who have contributed data should have access to implementation research findings.
- 10.64 Participants who acted as controls should gain access to interventions which were withheld from them during the study.

⁷⁰ Here, the terms 'horizontal' and 'vertical' refer to two levels or modes of integration, which are general and specialised respectively. An intervention integrated in the healthcare system vertically may, for example, target only a select group of patients. However, a public health intervention integrated horizontally will be applied broadly and be accessible to as much of the population as possible.

- 10.65 The results of implementation research should be disseminated irrespective of the results.
- 10.65.a Both negative and positive implementation research findings may be important for planning similar interventions elsewhere, and could enhance resource utilisation globally.
- 10.66 Knowledge generated in implementation research should be translated into public health action.
- 10.66.a Potential barriers to knowledge translation include lack of prior consultation with policy-makers, lack of funding, weak health systems, and absence of a culture of evidence-based decision-making.
- 10.67 Researchers should communicate their findings promptly to policy-makers and health system officials.
- 10.68 Researchers should propose actionable suggestions based on their research findings to facilitate uptake and scale-up of successful interventions.
- 10.68.a Barriers identified during IR may require further study to develop strategies to overcome them.
- 10.69 Knowledge generated in implementation research should be used for public education.
- 10.70 The interventions demonstrated to be successful in implementation research should be sustained post-research.
- 10.70.a Responsibility for sustainability lies with all stakeholders.
- 10.71 The benefits of implementation research should be shared regardless of context.
- 10.71.a Benefits may be direct as a result of the intervention being studied, or indirect and not related to the intervention. Benefits may also accrue to individual participants – for example therapeutic benefits – or to the community as a whole – such as knowledge about barriers affecting better provision of care. Direct benefits are shared by the sustainable translation of research into action, and indirect benefits by capacity-building and health system strengthening.
- 10.71.b Optimal benefit sharing is important in IR where the individuals who bear the risk do not receive direct benefit from the intervention.

Translational research

The definition of translational research is less clear than the definitions of basic and clinical research (Weijer et al. 2012). Translational research fosters the multidirectional

integration of basic research, patient-oriented research, and population-based research, with the long-term aim of improving the health of the public. One form of translational research expedites the movement between basic research and patient-oriented research that leads to new or improved scientific understanding or standards of care. The second form of translational research facilitates the movement between patient-oriented research and population-based research that leads to better patient outcomes, the implementation of best practices, and improved health status in communities. The third form of translational research promotes interaction between laboratory-based research and population-based research to stimulate a robust scientific understanding of human health and disease.

An important component of translational research concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

Most ethical considerations of a translational research programme are common to any research involving human subjects.

10.72 The interests of participants in translational research must always have priority over those of the wider community for whom the research benefit is envisaged. The objective of rapid knowledge transfer from basic research to clinical practice must not compromise participant safety.

10.73 Translational research should focus on diseases with high health impact and significant outcome inequity.

Innovative practice

Innovation in practice in health and disability care is a change to practice aimed at providing improvements in the outcomes or experiences of people receiving health or disability services.

Innovative practice sits on a continuum with normal or everyday practice. Health and disability services must always be tailored to the individual needs, circumstances and conditions of each consumer. The care of individual patients may therefore vary around a core of standard accepted practice.

Health professionals must be allowed to make minor deviations from accepted practice to adjust health care to suit the individual needs of each consumer, and sometimes new techniques or procedures may result from unplanned responses to medical complications arising from the treatment of an individual consumer.

However, innovative practice proper arises where there is a planned deviation from the currently accepted practice involving an untested or unproven intervention or change that is intended to be used on an ongoing basis (Ministry of Health 2008). An innovative practice may arise from a series of small incremental changes to accepted practice; practice becomes properly innovative where it reaches a point of significant shift, and the service provider plans to continue it.

The term 'innovative practice' extends to the application of known procedures in new or novel circumstances in which those procedures have not previously been tested. It may involve new delivery practices by health practitioners, or by those working in the disability field; new devices; new investigative procedures; new management options; or systems changes.

Ethical obligations involving innovative practice that does not meet the criteria for research

Where innovative practice does not require formal research, ethical obligations remain. For example, service providers should generally seek fully informed consent to the use of innovative surgical techniques or devices. A recognised danger in this area is that practitioners – and patients – may tend to believe that if something is new it is necessarily better. This belief may not be well founded; service providers need to make this clear to patients. To reduce the risk of false belief, the innovator may not always be the best person to seek consent.

10.74 To protect clinicians and patients, service providers should seek peer appraisal of innovative approaches.

10.75 Service providers should keep good records of the nature of innovations, the outcomes of their use for the patients, and developments and refinements.

10.76 Providers should clearly describe innovations and investigate ways to inform the wider community of health providers about the innovations being practiced. The recognised danger of runaway diffusion⁷¹ (Jake Earl 2019) needs also to be guarded against.

Conducting innovative practice

10.77 Only those with appropriate qualifications and expertise must undertake innovative practice, and only for the purpose of improving outcomes or experience for an individual consumer or consumer group.

⁷¹ Runaway diffusion refers to innovations which, due to non-therapeutic factors such as enthusiasm and profit, are adopted without adequate ethical oversight or scientific due process.

- 10.78 Appropriate safeguards should be in place to ensure that independent assessment occurs through an innovative process so that should it become apparent the innovative practice is not achieving positive results or is exposing consumers to unnecessary harm, service providers can resume providing standard practices.
- 10.79 Service providers must not prematurely adopt innovative practice into standards of care. They should put appropriate evaluative mechanisms in place to assess the effectiveness of any innovative practice; these may include formal research.

Research into innovative practice

- 10.80 Where innovative practice in health or disability services requires research, the practitioners involved must ensure this happens at the appropriate time and in the appropriate way.
- 10.80.a Research into innovative practice must meet these Standards, including the requirement for ethical review.
- 10.81 It can be challenging to identify when a difference from existing practice requires formal research, and what the nature of the research should be. As a guide, service providers should consider formally researching an innovative practice 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 may broaden health or disability sector inequities
 - the innovative practice represents a considerable or great degree of risk
 - the innovative practice represents the testing of a theory (or, even more informally, a hunch).
- 10.82 Service providers may not need to conduct full research on minor innovations.
- 10.82.a While it is beyond the scope of this discussion to fully specify such guidelines, some reasons that could justify engaging in innovative practice rather than clinical research include:
- the health condition addressed by the intervention occurs sufficiently infrequently that research is unnecessary or infeasible.
 - the intervention is in a relatively “early” stage of development, such that the clinician is likely to make significant changes depending on patient outcomes.

11 Research conduct

Introduction

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 their study activities. Conducting research responsibly is critical to achieving research excellence, and to maintaining public trust in health care. This chapter focuses on the essential aspects of responsible research conduct in relation to participants.

Overall responsibility for a study

- 11.1 The principal researcher or sponsor of a study has primary responsibility for the conduct of the study (including compliance with relevant law, regulations and guidelines) in New Zealand.
 - 11.1.a In this context, the essential duty of a research institution extends only to educating researchers on how to conduct research responsibly and ethically.

Clinical trial registration

- 11.2 In the case of clinical trials, researchers must register their study in a WHO-approved clinical trial registry before commencing the study. They should also provide results of the study to the public database of the registry.
 - 11.2.a Registering research promotes transparency, reduces publication bias, avoids unnecessary duplication, reduces the burden on participants and prevents the suppression of data in research (Canadian Institute of Health Research et al. 2014).
 - 11.2.b While this Standard focuses on clinical trials, transparency and reduction of unnecessary duplication and reporting bias are important for other types of research including public health intervention studies, observational studies, implementation research and pre-clinical studies of experimental therapeutics and preventives.

Whakapapa

Researchers have a primary duty of care to participants throughout the life cycle of a study, under the Te Ara Tika principle of whakapapa.

- 11.3 Researchers must safeguard the health and welfare of participants during their study.
- 11.3.a Whakapapa is an analytical tool for understanding why relationships have been formed and for monitoring how those relationships progress and develop over time. A common saying amongst Māori is “mai i te whai ao ki te ao Mārama” (“from the dawn light to the bright light of day”) which is a metaphor for understanding or enlightenment. In the context of decision-making, 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 ethical researcher conduct.
- 11.4 Researchers must also ensure that participants experience no gaps in care when their study participation concludes.

Identifying potential participants

Effective recruitment is critical; researchers must enrol a sufficient number of participants to reliably answer their study questions.

- 11.5 To select study participants, researchers must use a fair, equitable process, and include ethnic, educational, socioeconomic and gender diversity appropriate to the health or disability condition under study.
- 11.5.a 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. This method entails certain benefits: researchers can be sure that those they approach are potentially eligible, that research options are available to potentially eligible people so they may consider participation, and individuals are not exposed to risks unnecessarily. Researchers may use this method provided that:
- the use of records has been authorised by the individual or a waiver has been granted by an ethics committee
 - 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 for the purposes of this process 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 or to undertake an assessment of eligibility.

11.6 In some cases, an outside researcher may wish to review records or obtain lists of patients, medical records, test results or other clinical information, so that they can approach potential participants. Such a researcher must be able to justify how this review is ethical **without gaining prior consent** from the individuals linked to the health records concerned.

Recruitment methods

Many methods of recruiting participants are available to researchers. A chosen method must be 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.

The same standards apply if a patient (or their family or friends) approaches their health practitioner or a researcher about participating in a study.

Approaching potential participants

11.7 Researchers must choose a method of selecting and approaching participants that avoids unduly influencing potential participants.

11.7.a Depending on the study question and design, researchers may approach a potential participant directly (e.g. by advertisement, telephone or letter) or indirectly (e.g. through the participant's own doctor or relevant health professional).

11.7.b 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. In some cases, the first contact may be a referral to someone who is knowledgeable.

- 11.7.c When patients are recruited as prospective participants, the people directly involved in their care should make the first approach, rather than researchers the patients do not know. In limited circumstances, it may be justifiable for both the researcher and the health care provider to make the first approach (e.g. in a joint letter), or for the researcher to do so with reference to the health care provider.
- 11.7.d In terms of different approaches to recruitment, relevant considerations include whether the method used would put undue pressure on people to participate (or not participate) due to the power imbalance between clinician and participant; confidentiality (the clinician will know who the potential participants are already); and potential bias when the clinician makes decisions about who is a suitable candidate for the research (e.g. they may exclude participants because they think they are too difficult to involve, they disagree with their viewpoint or they assume the person may not be interested).
- 11.8 Incentives offered for participation in research 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 costs to participants to an ethics committee, ensuring that they avoid discrimination and that recruitment is fair.
- 11.9 All recruitment efforts must respect personal rights to privacy and confidentiality, comply with health information privacy regulations and avoid unduly influencing participants.

Advertising

- 11.10 Advertisements seeking participants for a study should not inflate the potential benefit of participation or imply that a health outcome is certain.
- 11.11 The design of recruitment advertisements must avoid deceiving or unduly influencing potential research participants.
- 11.12 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

- an ethics committee approval reference, if relevant
- location
- time or other commitment required of participants
- the person or office to contact for further information.

11.13 Advertisements may include study remuneration but this must not be emphasised, especially when potential participants are vulnerable to financial incentives.

Social media

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 online social networks of current or potential participants
- managing online communication from and between participants.

11.14 When recruiting through social media, researchers should examine the terms and conditions of the websites they use, considering:

- the degree to which the social media venue is public
- whether the site places restrictions on its use for recruitment or research
- whether the site publicly discloses tracking and data-mining activities to potential users before they join
- whether the online identity and real-world identity of potential participants are the same
- the contractual expectations the site has of its users, including 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.

11.15 Researchers should not disclose a participant’s sensitive information to others without that participant’s explicit permission, nor 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.

11.16 Researchers should be mindful of the values and potential vulnerabilities of people they approach on social media.

11.17 Researchers must be transparent in their use of social media for active recruitment. They must avoid [deception](#), and should not fabricate 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.

- 11.17.a Where a researcher has gained permission from a moderator or site administrator to recruit participants, this permission should be advertised on the site.
- 11.18 Researchers must 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.
- 11.19 Researchers should obtain 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

- 11.20 In considering the possibility of undue influence in research involving financial or other incentives, researchers should be sensitive to issues such as participants' economic circumstances, age and capacity; the customs and practices of the community involved; and the magnitude and probability of harms.
 - 11.20.a 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; for example, through travel costs and parking charges.
- 11.21 Researchers should avoid exploitation by not paying participants enough for their time.
- 11.22 Researchers should state at the outset of the study in what circumstances participant withdrawal will affect payments or koha, and what that effect will be.

Managing conflicts of interests or role conflict

- 11.23 Researchers must identify and minimise any conflict of interest or commitment (or perception of such conflict).
 - 11.23.a In the research context, a conflict of interest is 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.

- 11.23.b Researchers must identify real, potential and perceived conflicts of interest, and then manage, reduce or eliminate them. They must assess conflicts of interest in terms of both their likelihood and their consequences. Proper management of a conflict entails full and prompt disclosure (to an ethics committee, participant or other researchers) and implementation of appropriate safeguards, such as modifying the research plan or arranging for independent monitoring.

11.23.c Financial conflicts of interest are the most visible and measurable type of conflict, but 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.

Conducting research on one's own patients can be a legitimate way of creating knowledge for researchers and participants. However, dual-role researchers can face significant ethical challenges, involving issues such as undue influence, compromising the voluntary nature of participation, informed consent and privacy.

11.24 Researchers should consider options for managing these issues, including:

- enrolling patients who are in the care of another health care provider in the research, instead of the practitioner's own patients
- using an independent person to explain the study to participants and obtain their consent
- recognising and declaring the conflict, and mitigating the risks to [informed consent](#).

Safety and Data Monitoring

Most studies involving human participants require 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: trial oversight committees, coordinating centres or database monitoring, and on-site monitoring.

11.25 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.

11.25.a Any safety monitoring plan should include a mechanism by which researchers may remove participants for safety reasons. It should also provide a way of pausing or stopping 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.

11.26 Informal data safety monitoring is more likely to be appropriate in a single centre setting, either in minimal/low-risk observational studies or clinical trials with no dose escalation planned and using previously assessed dose regimen(s).

Trial oversight committees may include one or more of the following

- **A trial steering committee**
which provides overall supervision of the trial and ensures that it is being conducted in accordance with the principles of good clinical practice. The committee may have members who are independent of the researchers, including consumer representatives or laypeople or members of the relevant community who are able to provide a view representative of the community.
- **A trial management committee**
which is responsible for the day-to-day management of the trial. Every clinical trial should have a trial management group. Members often include the statistician, the trial coordinator, the data manager and the research nurses; however, in small, simple studies this 'group' may comprise just the principal researcher.
- **A data and safety monitoring committee (DSMC)**
exists to protect the safety of a study's participants, the credibility of the study and the validity of the study results. It 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 sponsors. Normally, the DSMC should have sole access to the data emerging in the study. The DSMC 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 not to have a DSMC.

A DSMC is generally an independent body, although in some circumstances it may be internal to the study and include representation from the trial steering committee and/or the study sponsor.⁷²

11.27 Table 11.1 indicates the most appropriate form of DSMC monitoring for different types of intervention studies.

11.27.a Members of the DSMC, especially the chair and the biostatistician,⁷³ should have prior DSMC experience.

⁷² For further guidance about operating plans for DSMCs, see information on the HRC's website <http://www.hrc.govt.nz/ethics-and-regulatory/data-monitoring-core-committee>

⁷³ The biostatistician has a multi-faceted role in clinical trials and is responsible for such as things as defining the sample size of research and, in relation to participant safety, planning and undertaking interim analysis.

Table 11.1 – Forms of DSMC monitoring for different types of intervention studies

| 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 trials (any phase) | Unlikely | Likely | Unlikely ³ | Maybe ² |
| Non-randomised trials | Unlikely | Unlikely | No | Unlikely |
| <p>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.</p> <p>2 An internal DMC would be advisable if an independent DMC is not established.</p> <p>3 Integrity/credibility issues could motivate the use of an independent DMC; for example, if a trial in this setting were to impose interim monitoring of comparative data.</p> | | | | |

Coordinating centres or database monitoring

A trial coordinating centre monitors data as it enters the database during the trial. Such 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.

11.28 The coordinating centre should monitor all trials to ensure integrity of study data.

11.29 An on-site monitoring process involves monitors visiting study sites to check adherence to study protocol and good clinical practice guidelines. This monitoring normally includes checking informed consent and eligibility, checking data on study case report forms against source data, and checking adverse event reporting.

11.29.a The appropriate extent of on-site monitoring depends on factors such as degree of risk, complexity of the study, study blinding and the experience of sites.

Responsibilities for adverse event monitoring

Every study must have a mechanism in place for responding to potential safety concerns.

11.30 In general, reliable interpretation of safety signals requires an interim report on safety and efficacy, in a form unblinded by intervention arm.

- 11.30.a Any study with potential for serious treatment-related adverse events must have a mechanism in place for promptly reporting, recognising and responding to serious adverse events and suspected unexpected serious adverse reactions and unexpected serious adverse reactions (SUSARS).
- 11.31 The protocol and/or monitoring plan of any study should state the study’s processes and responsibilities for identifying, coding, analysing and reporting adverse events.
- 11.31.a The degree of monitoring should be proportionate to the risk and complexity of the study.
- 11.32 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 11.2 for definitions of key terms in relation to adverse event monitoring.
- 11.33 Researchers should prioritise prompt reporting of SUSARs.

Table 11.2 – Key terms in adverse event monitoring

| Term | Definition |
|--|--|
| Adverse event | An event with negative or unfavourable reactions or results that are unintended, unexpected or unplanned. In practice this is most often understood as an event which results in harm or has the potential to result in harm to the participant. |
| Adverse drug reaction⁷⁴ | Any untoward and unintended response in a subject to an intervention that is related to any dose administered to that participant. |
| Unexpected adverse reaction | Any 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, serious adverse drug reaction or unexpected serious adverse reaction | Any adverse event, adverse drug reaction, or unexpected adverse reaction, that: <ul style="list-style-type: none"> • results in death • is life-threatening • requires inpatient hospitalisation or results in prolongation of existing hospitalisation • results in persistent or significant disability or incapacity • 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

⁷⁴ For guidance on reporting adverse events in New Zealand see <https://www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2937/>

Terminating a study

- 11.34 In some circumstances, it may be appropriate to end a study early.
- 11.35 For any study that has a data safety monitoring committee (DSMC), the monitoring plan should contain criteria and processes for early termination of the study. If the study is ended early, the process for termination should follow the study's monitoring plan and the advice of the DSMC.
- 11.36 For any study that does not have a DSMC, the study's monitoring plan should comment on the conditions under which early termination of the study would be considered.
- 11.37 Therapeutic studies where participants are potentially receiving therapeutic benefit must not be terminated simply for reasons of commercial interest.

New information

Researchers must promptly report new information that may affect the safety or ongoing consent of participants to appropriate regulatory bodies and to participants.

- 11.38 When a researcher identifies new information that may impact on participants, they must review affected aspects of the research to ascertain whether participants are adversely impacted. If they are, researchers must make changes to the study to remedy this.
- 11.39 New information includes:
- changes to the research design
 - evidence of 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.
- 11.40 In cases where the new information contains acute safety information, informing participants of the new information should not be delayed by the development and approval of updated informed consent documents.

Disclosing information

Researchers' responsibilities to inform other health professionals of a participant's research involvement depend on the nature of the research. Certain areas of research (eg, research involving children at risk of abuse or studies of criminal behaviour) are more likely to put researchers in positions of tension between the ethical duty of confidentiality and a duty to disclose particular information to third parties.

11.41 Researchers must protect individuals' privacy and confidentiality.

11.41.a The only exception to this is where they have an overriding ethical concern (for example, the health or safety of participants or others) justifying the release of participants' information, or where such release is required by law. If researchers must breach privacy or confidentiality, they should first make a reasonable attempt to inform participants of the breach.

11.42 Researchers should be aware of ethical codes or laws that may require them to disclose certain information they may gain as researchers (e.g. suspected abuse), and of where to report such information.

11.43 In such situations, researchers should decide on appropriate conduct on a case-by-case basis, in consultation with colleagues, relevant professional bodies and legal advisors, as relevant, taking into account the requirements of the [Health Information Privacy Code 1994](#).

11.44 In certain situations, in the interests of the safety and wellbeing of a particular participant, researchers should, with the participant's consent, inform the health professional responsible for that person's health care about the person's participation (usually at the time of enrolment in the research), and any possible health implications of this involvement.

11.44.a If a participant withholds their consent to contact the health professional, the researcher should consider whether it is ethical to enrol the participant in the study.

11.44.b In other situations, informing relevant health professionals is desirable if the participant consents, but is not mandatory for safety.

Returning results and incidental findings

Incidental findings are observations of potential clinical significance that are unexpectedly discovered in research. 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. Researchers have a duty or

responsibility to inform participants of such findings, arrange counselling (e.g. genetic counselling or mental health counselling) for them if necessary and ensure adequate follow-up. In some cases, researchers themselves may not know if incidental findings are clinically relevant, particularly in the case of genetic findings. Follow-up may involve referring participants to a suitable health professional or specialist.

11.45 Researchers should inform participants of any expected or possible implications of the study analysis.

11.45.a For example, individual study results may impact on a participant's ability to obtain insurance, employment or loans, and may also have social implications (e.g. by revealing previously unknown paternity information).

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

11.47 The protocol must set out what will happen should such information be available, and this information should be included in the information provided to participants prior to obtaining their informed consent.

11.48 Before conducting research, researchers must develop and record a plan for how they will handle incidental findings.

11.48.a In developing such a plan, researchers should consider whether to communicate to participants findings that are not clinically actionable, noting that participants have the right to information that a reasonable participant in that participant's circumstance would expect to receive, including being informed of the results of tests ([Code of Health and Disability Services Consumers' Rights 1996](#)).

11.49 Researchers should give participants the choice of opting out of receiving individual results of analyses that are not clinically significant, or for which treatment is not available.

11.49.a 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 at their final study visit.

11.49.b In this case, researchers should signal to participants when they enrol that they will be routinely asked to reaffirm their informed consent at the second point, and that this request will not be due to the nature of their results.

Communicating and disseminating research results

Communicating study results is essential, to realise the merit of the research.

- 11.50 Researchers must report their research results accurately, with integrity and in a timely manner, whether the results are positive or negative.
- 11.51 Researchers must release their results in a way that recognises cultural sensitivities, avoids stigmatising individuals or groups and does not identify individual participants without their consent.
- 11.52 Researchers must offer participants a summary of research results that is written for non-specialists in plain language.
 - 11.52.a Researchers should avoid sending participants a link to study results that are behind a pay-wall.
- 11.53 Researchers should communicate their study results in a time-sensitive and appropriate way, so that benefits to the community are maximised and fairly distributed.
- 11.54 Researchers should not enter into contracts that limit, or apply unreasonable time restrictions to, the release of research results.
 - 11.54.a Any proposed restrictions on publications must include an ethically acceptable justification; for example, in limited circumstances, where a study intervention is in the product development cycle. The onus to justify restrictions on disseminating or accessing data lies with the party seeking to make the restriction.
 - 11.54.b 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.

Interpreting and presenting study results

- 11.55 Researchers must strive to report study results accurately. They should anticipate and avoid misinterpretation of those results.
- 11.56 Conflict may arise for researchers between doing no harm and openly disclosing research results. In this case, researchers must attempt to present data in a way that protects the interests of those at risk while it maintains research integrity.
 - 11.56.a In framing their analyses, researchers must avoid deficit thinking (a catch-all term for theories conjecturing that poor health outcomes are the fault of people's ethnicity, sexuality, gender, culture and/or socioeconomic status). For example, researchers must not look on the health disadvantages Māori experience as inherent to Māori ethnicity.
 - 11.56.b Similarly, analysis of the causes of disparities experienced by disabled people 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 aim to provide analysis that brings advantages and opportunities to the groups under study, and therefore help to counteract negative stereotypes.

11.57 Researchers must avoid deficit thinking.

11.57.a Deficit thinking is an important component of research that focuses on improving outcomes for Māori. Including Māori researchers in decision-making roles within the research team can help to address this risk.

11.57.b It is the responsibility of the research team as a whole to ensure that the study is ethical. In this context, effective localised relationships are a very important part of ensuring results are interpreted correctly. See 'Research and Māori' for more information.

Timing the release of results

If research results are not communicated within a reasonable time, their value may be diminished or lost, and the value of participants' contributions reduced. 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.

11.58 Where making results available would immediately benefit participants, researchers are responsible for making results available to those affected as soon as practicable.

Releasing all results

11.59 Releasing all research results helps to prevent reporting bias. It is normally not appropriate to release incomplete research results (e.g. release of early results, secondary end-point results or results from only some research sites), because such results may be misleading.

11.60 Researchers must also effectively communicate negative results, because these too add to collective knowledge, and may allow other researchers studying the same intervention to avoid wasting resources.

Charging participants

People who are already burdened by poor health or disability are in general a **potentially vulnerable** group. Asking them to contribute money in exchange for being involved in research raises serious concerns about justice, autonomy and the potential for exploitation.

- 11.61 Researchers may be able to justify charging participants to receive trial products or procedures in a very limited set of circumstances, including where:
- researchers have explored all other options to raise funds for the research
 - the research has a very high likelihood of generating benefit to a population with serious unmet needs
 - 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, so that participants are fully aware that they are paying to participate in a study that aims to provide social value through generalisable knowledge
 - evidence indicates that 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.

Maintaining the safety of researchers

- 11.62 Researchers may sometimes be required to undertake activities in situations that put themselves at risk. For example, they may need to interview participants in their own 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.
- 11.63 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 to a meeting with a participant.
- 11.64 It is not usually acceptable for researchers to use their own homes to conduct research with participants.
- 11.65 Researchers travelling overseas need to be familiar with how best to conduct research within the culture and jurisdiction to which they are travelling.

12 Health data

Introduction

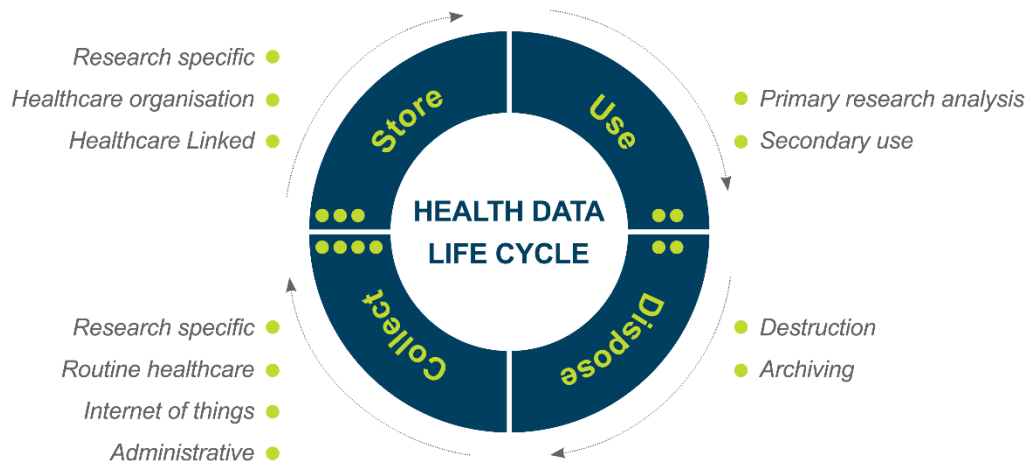
In the New Zealand context, data is seen as taonga (something sacred, precious, or significant) (Whaanga et al. 2017). A taonga should be actively cared for in a manner that preserves its integrity and value. Health data is used in most health and disability research studies, as well as QI projects. Some of this data is prospectively collected for the purpose of research, but a growing proportion of data is collected through routine processes, for example through healthcare procedures or interaction with health agencies.

Data exists in both analogue (paper) and digital (electronic) formats. Increasing digitisation means data is being collected from both 'traditional' sources such as administrative data, electronic health records, as well as novel sources like apps, fitness trackers, cellular phones, social media (Internet of Things, IoT). Digital infrastructures are allowing person-level linkages between healthcare and non-healthcare data, allowing unique insight into the social determinants of health. This section adopts a broad definition of these data sources and is intended to encompass all sources and types of data described in these Standards as 'Health Data'. These standards should be adhered to by all researchers who hold and use data within this broader context.

The life cycle of health data includes collection, use, analysis, publication, storage, curation, and destruction (Figure 12.1). This chapter provides ethical guidance on collecting new data from participants and/or individuals and accessing and reusing data that has already been collected (for example, from clinical records, other research projects or administrative data⁷⁵).

⁷⁵ Administrative data can be defined as data that is collected by government agencies or private organisations in the course of conducting their business or services

Figure 12.1 – The life cycle of health data



Storing data often involves elements of security, governance and management, privacy, consent, and curation. Data can be used in a variety of ways: to explore concepts or answer the specific questions that prompted the collection of data in the first place; or, to explore concepts or answer questions formulated after the collection of data – this latter concept is referred to as “secondary use”. Data may be used for future studies and projects, including those which are unspecified, and data use may also occur through databanks (Data Registries). Lastly, data is disposed of: this disposal can take the form of destruction, or as is more often the case, either time-limited or indefinite archiving (for example, for regulatory compliance purposes).

Beyond these ethical standards, researchers must comply with current relevant standards for data governance and security.⁷⁶ At present, these include (1) the “Digital, data and technology services – minimum requirements”; (2) “HISO 10029: 2015 Health Information Security Framework”; and (3) “HISO 10064:2017 Health Information Governance Guidelines”, the latter of which highlights some key elements of data quality, privacy, privacy breach, and secondary use of data that are relevant to these standards. It is the obligation of researchers to ensure that they are up to date with current data privacy, governance, and security standards in New Zealand.

⁷⁶ See <https://www.health.govt.nz/our-work/digital-health/digital-health-sector-architecture-standards-and-governance/health-information-standards-0>

General considerations for data collection and re-use of existing data

The following standards apply to both new data collection and re-use of existing data.

Māori data

Māori data refers to data produced by Māori or that describes Māori and the environments they have relationships with. Māori data includes but is not limited to:

- data from organisations and businesses
- data about Māori that is used to describe or compare Māori collectives
- data about Te Ao Māori that emerges from research.

12.1 Māori should be involved in decisions about the primary collection, analysis, and interpretation of Māori data in research contexts.

12.2 Decisions about governance and access to data for secondary purposes should be consistent with the Māori Data Sovereignty principles, developed by Te Mana Raraunga⁷⁷ below. While these principles were developed for Māori data, their application to all health data is recommended, and reflects good practice.

⁷⁷ See <https://www.temanararaunga.maori.nz/> for more information.

Māori Data Sovereignty principles

Rangatiratanga | Authority

- **Control**

Māori have an inherent right to exercise control over Māori data and Māori data ecosystems. This right includes, but is not limited to, the creation, collection, access, analysis, interpretation, management, security, dissemination, use and reuse of Māori data.
- **Jurisdiction**

Decisions about the physical and virtual storage of Māori data shall enhance control for current and future generations. Whenever possible, Māori data shall be stored in Aotearoa New Zealand.
- **Self-determination**

Māori have the right to data that is relevant and empowers sustainable self-determination and effective self-governance.

Whakapapa | Relationships

- **Context**

All data has a whakapapa (genealogy). Accurate metadata should, at minimum, provide information about the provenance of the data, the purpose(s) for its collection, the context of its collection, and the parties involved.
- **Data disaggregation**

The ability to disaggregate Māori data increases its relevance for Māori communities and iwi. Māori data shall be collected and coded using categories that prioritise Māori needs and aspirations.
- **Future use**

Current decision-making over data can have long-term consequences, good and bad, for future generations of Māori. A key goal of Māori data governance should be to protect against future harm.

Whanaungatanga | Obligations

- **Balancing rights**

Individuals' rights (including privacy rights), risks, and benefits in relation to data need to be balanced with those of the groups of which they are a part. In some contexts, collective Māori rights will prevail over those of individuals.
- **Accountabilities**

Individuals and organisations responsible for the creation, collection, analysis, management, access, security, or dissemination of Māori data are accountable to the communities, groups, and individuals from whom data derives.

Māori Data Sovereignty principles – continued

Kotahitanga | Collective benefit

- **Benefit**
Data ecosystems shall be designed and function in ways that enable Māori to derive individual and collective benefit.
- **Build capacity**
Māori Data Sovereignty requires the development of a Māori workforce to enable the creation, collection, management, security, governance and application of data.
- **Connect**
Connections between Māori and other Indigenous peoples shall be supported to enable the sharing of strategies, resources and ideas in relation to data, and the attainment of common goals.

Manaakitanga | Reciprocity

- **Respect**
The collection, use and interpretation of data shall uphold the dignity of Māori communities, groups and individuals. Data analysis that stigmatises or blames Māori can result in collective and individual harm and should be actively avoided.
- **Consent**
Free, prior and informed consent (FPIC) shall underpin the collection and use of all data from or about Māori. Less defined types of consent shall be balanced by stronger governance arrangements.

Kaitiakitanga | Guardianship

- **Guardianship**
Māori data shall be stored and transferred in such a way that it enables and reinforces the capacity of Māori to exercise kaitiakitanga over Māori data.
- **Ethics**
Tikanga, kawa (protocols) and mātauranga (knowledge) shall underpin the protection, access and use of Māori data.
- **Restrictions**
Māori shall decide which Māori data shall be controlled (tapu) or open (noa) access.

Data identifiability

There are a number of different levels of data identifiability and terms used to describe them.

- 12.3 Researchers must accurately describe the identifiability of data to obtain meaningful informed consent and to determine the ethical risk of their studies. HISO 10064:2017⁷⁸ describes the levels of data identifiability, Table 12.1.

Table 12.1 – Levels of data identifiability

| Identifiable data | |
|--|--|
| Data from which it can reasonably be assumed that it is possible to identify a specific individual involved in the study | |
| <p>Direct identifiers</p> <ul style="list-style-type: none"> ● NHI ● Name ● Street address ● Phone number ● Online identity (e.g., email, twitter name) ● Identification numbers (e.g., community services card, driver's licence). | <p>Indirect identifiers</p> <ul style="list-style-type: none"> ● Date of birth ● Identification of relatives ● Identification of employers ● Clinical notes ● Any other direct or indirect identifiers that carry significant risk of re-identification. |
| Non-identifiable data | |
| There are two levels of non-identifiable data: de-identified data and anonymised data | |
| <p>De-identified data</p> <ul style="list-style-type: none"> ● The fields listed under the definition of identifiable data are excluded, and ● Fields that might be used for deliberate re-identification are included, such as: <ul style="list-style-type: none"> ● encrypted NHI or study codes ● year of birth or age in years at a given date ● event dates ● gender ● ethnicity (Level 2 as defined by Statistics New Zealand) ● mesh block or suburb ● deprivation index | <p>Anonymised data</p> <p>A precise definition of anonymised data has become more difficult because methods to re-identify data are rapidly evolving. Researchers should assume that all data is potentially re-identifiable and maintain governance and guardianship to this standard.</p> <p>A minimal operational standard of anonymity should:</p> <ul style="list-style-type: none"> ● Exclude fields listed under the definition of identifiable or de-identified data, and ● Obfuscate data to minimise re-identification risk, including but not limited to the following measures: <ul style="list-style-type: none"> ● disclosure of the bare minimum data set for purpose ● use of 5–10-year bands rather than dates ● aggregation of ethnicity data (level 1 as defined by Statistics New Zealand) ● blurring of geographic data (by area unit or city) ● exclusion of low-frequency characteristics useful for re-identification (e.g., rare medical conditions) ● strong consideration of more technical assessments or approaches such as k-anonymity ≥5, federated learning, differential privacy. |

⁷⁸ <https://www.health.govt.nz/publication/hiso-100642017-health-information-governance-guidelines>

Re-identification

For the purposes of these Standards, data should be stored, utilised, and disposed of on the assumption that it is potentially re-identifiable.⁷⁹

- 12.4 Researchers must identify and assess risks related to re-identification and implement measures to mitigate those risks through de-identification of data and obfuscation
 - 12.4.a Data analysis involving data integration and linking may heighten risks of re-identification. Such a risk is greater if the study relates to a population in a small geographical area, or to individuals with unique characteristics, where a large number of variables relate to an individual.
 - 12.4.b Researchers should give special consideration to the question of whether data being retained for future use needs to be kept identifiable.
- 12.5 Whenever studies using re-identifiable data reveal information that affects the health and wellbeing of participants and/or individuals (see 'Returning results and incidental findings'), researchers must consider how to make that information available to the participants and/or individuals, if the participants and/or individuals have consented to receiving such information.

Benefits and harms from data use

Health data can generate benefits for individuals and the public both now and in the future. In some cases, it may be unethical not to use data because it may deny these benefits, and a failure to use it may also cause harm. 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.

The nature, degree, and likelihood of benefits resulting from studies is dependent on context, which researchers must consider every time they propose to use health data.

The nature, degree, and likelihood of possible harms resulting from studies also depends on context, which researchers must also consider every time they propose to use health data.

Table 12.2 lists some of the main types of potential harms from the use of health data.

⁷⁹ <https://privacytools.seas.harvard.edu/publications/reidentification-risks-hipaa-safe-harbor-data-study-data-one-environmental>.

Table 12.2 – Some potential harms from use of health data

| Type of harm | Indicator |
|---------------------------------|--|
| Physical harm | <ul style="list-style-type: none"> Public attacks, spouse/partner abuse, domestic violence, delayed or inadequate treatment |
| Social harm | <ul style="list-style-type: none"> Discrimination, cultural harm, community discrimination, isolation, inability to access care or exclusion from care |
| Economic harm | <ul style="list-style-type: none"> 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 harm | <ul style="list-style-type: none"> Distress, trauma, stigma |
| Legal harm | <ul style="list-style-type: none"> Arrest, prosecution, expulsion, loss of insurance |
| Privacy harm | <ul style="list-style-type: none"> Participants and/or individuals not accessing services because they believe their privacy is at risk |
| Interpretation harm | <ul style="list-style-type: none"> Inappropriate conclusions, apophenia (reporting patterns that are not there), implied causality rather than correlation, unrecognised data-quality issues, digital misrepresentation (e.g. algorithmic bias) |

In light of these potential harms, the following general standards apply to the use of health data. More detailed standards also apply for some aspects, for example, the storage and protection of health data.

12.6 Researchers must justify health data use, recognising the ethical tension between respect for individuals or groups (according to principles such as privacy, confidentiality, dignity and autonomy) and beneficence (the advantages of generating new knowledge).

12.7 Researchers must identify the possible benefits and risks of harm of health data use, carefully balance them against each other, and consider how to minimise and mitigate any harms of data use.

12.7.a Studies involving health data should seek to minimise risks and maximise benefits. This applies to both prospectively collected data and previously collected data being used for a secondary purpose.

Privacy and confidentiality

The principles of privacy and confidentiality apply to all health data at all points of the data lifecycle.⁸⁰

⁸⁰ See also the SIA's information on data protection and use and data.govt.nz's Data Confidentiality Principles.

- 12.8 Researchers must record and respect restrictions that participants and/or individuals place on the use of their health data.
- 12.9 Researchers must protect participants' and/or individuals' health data and must only use and disclose it to people authorised by those participants and/or individuals, unless:
- disclosure of the data is required by law
 - 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, [Rules 10 (1) (d) and 11 (2) (d) HIPC]
- 12.10 Unauthorised disclosure plans should be in place that are compliant with HISO 10064:2017 Health Information Governance Guidelines⁸¹ and the Privacy Act,⁸² and adherent to organisational policies and procedures. This plan should include steps to reduce accidental disclosure and data breach, how to inform participants and/or individuals, as well as mitigation steps to limit the impact of accidental disclosure and data breach.

Storage, governance and management of data

Data can be stored in analogue or digital form. Regardless of the form of storage, health data storage must meet the following standards:

- 12.11 Health data should be stored in a secure manner. Examples of secure storage include: locked file cabinets in locked rooms; password protected databases located on computers in locked rooms; password protected databases via password protected computers; etc.
- 12.12 Researchers should weigh the benefits and risks of keeping identifiers on stored data.
- 12.12.a In some cases, there will be good reasons to maintain an identifier, or a link to an identifier (e.g. to maintain participant and/or individual safety, or to re-use the data).
- 12.13 Data should not be stored longer than is required for the purposes for which the information may lawfully be used, but should be stored for the minimum period required by New Zealand law (currently 10 years for health data that relates to an identifiable individual).

⁸¹ See <https://www.health.govt.nz/publication/hiso-100642017-health-information-governance-guidelines>

⁸² See <https://www.privacy.org.nz/the-privacy-act-and-codes/privacy-act-and-codes-introduction/>

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 the consent requirement for data use has been waived, where there is data linking, or where unspecified future use is intended. Māori control of Māori data is the primary goal for Māori data sovereignty by improving Māori/iwi access to data for governance decision-making and ensuring Māori/iwi involvement in governance of data.

Data can be primarily collected by a researcher, but in the modern healthcare environment organisations are often the primary data source. This creates a tiered structure of overlapping responsibilities of data guardianship between, on the one hand, organisations that create, store, and allow access to data and, on the other hand, individual researchers who use this data, who may work within or outside the data source organisation.

Organisational Guardianship

12.14 Organisations must establish proportional, appropriate and robust data governance and data management policies and procedures during the life cycle of data.

12.14.a Relevant current standards to which organisations must adhere include the “Digital, data and technology services – minimum requirements⁸³”, “HISO 10029: 2015 Health Information Security Framework⁸⁴”, and “HISO 10064:2017 Health Information Governance Guidelines.⁸⁵”

12.14.b This latter document highlights some key elements of data quality, privacy, privacy breach, and secondary use of data that are relevant to these standards.

12.14.c Issues an organisational data governance committee should consider include:

- the quality and reliability of data
- whether there is a social license for secondary data use; i.e. the ability of an organisation to use and share data in a legitimate and acceptable way, based on the trust that individuals have.
- details of the form (i.e., identifiable, de-identified or anonymised) in which health data will be collected, accessed, used and stored at

⁸³ See <https://www.health.govt.nz/our-work/digital-health/digital-health-sector-architecture-standards-and-governance/digital-data-and-technology-services-minimum-requirements>

⁸⁴ See <https://www.health.govt.nz/our-work/digital-health/digital-health-sector-architecture-standards-and-governance/health-information-standards-0/approved-standards/security-standards>

⁸⁵ See <https://www.health.govt.nz/publication/hiso-100642017-health-information-governance-guidelines>

the different stages of use, and measures proposed to remove identifying details

- policies for who will access health data and under what conditions
- policies for how consent will be sought for data collection and use, including secondary use. If data collection and use are unconsented, policies 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
- how the privacy and confidentiality of health data will be protected, including any circumstances in which it may not be possible to protect it, and any circumstances that may result in unauthorised disclosure of health data. Organisations should aspire for best in class in terms of data security and accountability⁸⁶.
- procedures for dealing with any breaches of privacy and confidentiality, including unauthorised disclosure of health data; measures that will be taken to notify those affected by the disclosure; and measures that will be taken to mitigate any harm caused by unauthorised disclosure
- named accountability for complying with requirements regarding the privacy and confidentiality of health data
- policies for how researchers accessing and using health data will be held accountable for complying with requirements regarding the privacy and confidentiality of that data
- procedures for the return of results, including incidental findings
- transparent policies for commercial use of health data and proposals for benefit sharing, including intellectual property issues
- whether health 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 and whether there will be New Zealand representation on overseas governance committees⁸⁷
- whether health data will be transferred to other institutions such as databanks and registries, and in that context who will access it, how it will be used (e.g., future uses and linking) and how privacy

⁸⁶ hardware/software/system policies, named individuals with accountability, standards (or near to) e.g. ISO27001, researcher registration, user training etc

⁸⁷ <https://snapshot.ict.govt.nz/guidance-and-resources/using-cloud-services/assess-the-risks-of-cloud-services/>

and confidentiality will be protected and whether there will be New Zealand representation on overseas governance committees

- what measures will be adopted to ensure transparency across all aspects of the data life cycle.

Researcher Data Guardianship

12.15 Researchers and or institutions utilising data must establish proportional, appropriate and robust data governance and data management processes during the life cycle of data. This should complement organisational governance and management structures, but do not supersede those requirements.

12.15.a Researchers and or institutions must describe these frameworks in their protocol or associated documents, and they should include:

- the purposes of the data collection, and how data will be collected and by whom, including any training required for data collectors
- the proposed uses of health data, including any future uses, linking and other analytics that may result in harm to the participant and/or individuals or others, such as their families, whānau, communities and groups
- details of the form (i.e., identifiable, de-identified or anonymised) in which health data will be collected, accessed, used and stored during the data life cycle and measures proposed to remove identifying details
- who will access the health data and under what conditions
- plans for how consent will be sought for data collection and use, including secondary use. If data collection and use are unconsented, plans for seeking a waiver of consent from organisational data governance committee or 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 health data will be retained
- how the privacy and confidentiality of health data will be protected, including any circumstances in which it may not be possible to protect it, and any circumstances that may result in unauthorised disclosure of such data
- procedures compliant with organisational policies and procedures for dealing with any breaches of privacy and confidentiality, including unauthorised disclosure of health data; measures that will be taken to notify those affected by the disclosure; and measures

that will be taken to mitigate any harm caused by unauthorised disclosure

- named accountability for complying with requirements regarding the privacy and confidentiality of health data
- procedures for the return of results, including incidental findings.
- transparent plans for commercial use of health data and proposals for benefit sharing, including intellectual property issues
- whether health 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 and whether there will be New Zealand representation on overseas governance committees
- whether health data will be transferred to other institutions such as databanks and registries, and in that context, who will access it, how it will be used (e.g. future uses and linking) and how privacy and confidentiality will be protected and whether there will be New Zealand representation on overseas governance committees
- participant and/or individuals' rights to correct their data
- procedures for withdrawing participant and/or individuals' data
- details of proposed approaches for community engagement
- what measures will be adopted to ensure transparency across all aspects of the data life cycle.

Sending and or Storing Data Overseas

The New Zealand government has adopted a Cloud First policy, requiring agencies to accelerate their adoption of public cloud services as it pertains to digital data.⁸⁸ This adoption is on a case-by-case basis following risk assessment. In the case of research data, storage of digital and analogue data is normative. Data storage security and privacy principles should pertain to both analogue and digital data storage.

Researchers should be aware that digitally-transmitted and stored data may pass through jurisdictions outside New Zealand and be stored in facilities outside New Zealand. Researchers should be aware that data stored outside New Zealand is governed by local standards of data security and privacy protection, which may vary depending on local legal standards. The cloud risk assessment process and tools

⁸⁸ <https://www.digital.govt.nz/standards-and-guidance/technology-and-architecture/cloud-services/>

provided by digital.govt.nz⁸⁹ provide principles of data security and access control that should be considered by researchers using overseas or cloud-based data storage.

Identifiable data may be sent overseas for the purposes of research if the person from whom the data was collected has consented to it or if a waiver of consent is granted.

12.16 Researchers should consider whether it is possible, appropriate and practical to seek consent to store data overseas.

12.16.a If consent is being sought, researchers must ensure participants and/or individuals understand that privacy protections in other countries may be different to those offered in New Zealand and that there may be no New Zealand representation on overseas organisations which make decisions about data use.

Non-identifiable data may be sent overseas without consent where, due to the nature of the information, it is not possible, appropriate or practical to seek consent.

12.17 Generally, the risk of sending non-identifiable data overseas is lower than sending identifiable data; however, in this case researchers should consider the fact that:

- other countries may have lower levels of data protection than New Zealand, and
- overseas researchers are unlikely to work with data in a way that is culturally appropriate for the New Zealand context, or have connections or understanding of the communities that the data relates to. For example, they may not be aware of the importance of avoiding a deficit model when discussing health data related to Māori, Pacific peoples and other groups.

Directly-collected new data

These standards are about collecting new information from individuals or communities.

12.18 Researchers must collect new data from participants and/or individuals in a manner that is lawful and fair, and that does not intrude to an unreasonable extent on the personal affairs of participants and/or individuals (Rule 4, HIPC).

12.19 Researchers should pay attention to participants and/or individuals' preferences (e.g. they may wish to have whānau or family members present) and cultural sensitivities.

⁸⁹ <https://snapshot.ict.govt.nz/guidance-and-resources/using-cloud-services/assess-the-risks-of-cloud-services/cloud-computing-mitigating-risk/index.html>

- 12.20 Determining whether a particular means of collection is unreasonably intrusive may depend on the context and sensitivity of the information. For example:
- 12.20.a information may be particularly sensitive where it relates to a person's sexual life, ethnicity or HIV status; diseases or conditions carrying social stigma; mental health; life expectancy; or addiction.
 - 12.20.b privacy may be at risk if the physical environment at the time of collection is a prison, rest home, school, educational institution, hospital or place of employment.
- 12.21 People collecting data must be suitably trained, experienced and culturally knowledgeable. If they are new researchers, they must be supported by a suitably trained, experienced and culturally knowledgeable person.
- 12.22 When collecting new data from participants and/or individuals, researchers must ensure that they are informed of, and consent to, the collection and use of their new data for the study.
- 12.22.a Note that this applies to the collection of new data. If a researcher is accessing identifiable or re-identifiable data that has already been collected, a waiver may be required.
- 12.23 Researchers must only collect data necessary for the specified purposes of their study.
- 12.24 Researchers must obtain consent from a participant and/or individual from whom data has been collected in a study ('the original study') to use that data for future studies.
- 12.25 Protocols, by design, should specify the category to which the future unspecified research falls under, and should provide adequate rationale as to how the risks and benefits justify the proposed future unspecified research. Additionally, protocols should specify if results arising for future research will be made available to the participant and/or individual.

Re-use of existing data

Increasingly, data that has been collected for a specific purpose, for example clinical care or administrative data through government agencies, is re-used and or linked for health research. These standards are about re-using data. For a further resource on the ethical secondary use of existing data, see [Stats NZ's Five Safes framework](#).

Determining sensitivity, level of consultation and level of data management

Table 12.3 below summarises key Māori concepts relevant to questions that help assess the level of sensitivity of the data, and the corresponding requirement to consult for re use, and the appropriate level of data management (Hudson et al 2017) ⁹⁰.

12.26 Taking into account the table below, 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.

12.27 Any such engagement should be transparent and fair, done in good faith, be truthful, and consistent with the concepts and practice of the Te Ara Tika principles.

Table 12.3 – Assess and determine data sensitivity

| Concept | Characteristic | Assessment Question |
|-----------|---------------------------|--|
| Tapu | Level of sensitivity | <ul style="list-style-type: none"> How sensitive is the data? |
| Noa | Level of accessibility | <ul style="list-style-type: none"> How accessible should this data be? |
| Tika | Level of value | <ul style="list-style-type: none"> How does the use of this data add value to the community? |
| Pono | Level of trust | <ul style="list-style-type: none"> Will the community support this use of the data? |
| Mauri | Level of originality | <ul style="list-style-type: none"> How unique is the data? |
| Wairua | Nature of the application | <ul style="list-style-type: none"> Is the data being used in the same spirit as its original use? |
| Whakapapa | Level of relationship | <ul style="list-style-type: none"> Does the user have an existing relationship with the data? |
| Pukenga | Level of expertise | <ul style="list-style-type: none"> Does the user have the expertise and experience to use data in a culturally appropriate manner? |
| Kaitiaki | Level of authority | <ul style="list-style-type: none"> Will the data be protected from inappropriate use? |
| Wānanga | Level of responsibility | <ul style="list-style-type: none"> Does the institution have the necessary infrastructure to ensure the use of the data in a culturally appropriate and ethical manner? |

Waiver of consent for secondary re-use of identifiable health data

Gaining informed consent to use previously collected identifiable data (including linking) should always be the default starting point. Where researchers propose to use

⁹⁰ "He Matapihi ki te Mana Raraunga" - Conceptualising Big Data through a Māori lens 2017

identifiable without specific consent for a study or project (e.g. where data was collected for care, or the proposed data use is not consistent with the scope of the original research consent), they must:

12.28 Satisfy national data standards and local data governance requirements.

12.29 Justify to an ethics committee that the nature, degree and likelihood of possible benefits (including to participant and/or individuals and the value of the research to the public) outweigh the nature, degree and likelihood of possible harms (including to any participant and/or individual, other individuals, whanau, hapu, iwi, Maori communities and any other groups or communities). In determining whether to grant a waiver of consent an Ethics Committees may also have regard to the following factors:

12.29.a There are scientific, practical, or ethical reasons why consent cannot be obtained.

12.29.b Appropriate data [governance](#) plans are in place.

12.29.c The researchers have identified whether consultation is required, and if required they have undertaken appropriate consultation with cultural or other relevant groups, and those consulted support the proposed use.

12.30 When considering a waiver, researchers should identify if there is any known or likely reason to expect that the participant and/or individual(s) would not have consented if they had been asked.

12.30.a It should be understood that a waiver of consent is not a waiver of responsibility, e.g. should there be an actionable incidental finding then it should be disclosed to the participant and/or individual.⁹¹

Data-linking

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 health outcomes (Data Linkage Western Australia 2019).

When data sets are linked, the risks of identification and adverse public reaction are likely to be greater, especially when the different data sources (which may apply to individual people, households or organisations), may have been designed and collected without the intention of using them together. The process may give rise to concerns that

⁹¹ Code of Health and Disability Services Consumers' Rights, Right 6.

the combined format produces a detailed picture of individuals that they did not consent to when they supplied the data. Privacy is a major consideration in data linkage work.

- 12.31 Researchers involved in data-linking must weigh the potential benefits of their research against the risk that individuals will be identifiable within their results. See ‘Benefits and harms from data use’ and ‘Research benefits and harms’.
- 12.32 Researchers must either seek consent from participants and/or individuals or obtain a waiver from a local data governance committee or an ethics committee for research that involves data-linking with identifiable and re-identifiable data.
- 12.33 Consent from participants and/or individuals or a waiver from an ethics committee is not required for use of linked non-identifiable data, but researchers should be aware of the type and size of data sets being linked, and how these factors increase the risk of identification.
 - 12.33.a Data linked by a third party at the request of a researcher, but provided in a non-identifiable format, is a way of controlling risk of re-identification in research involving linkage.
 - 12.33.b Use of linked data that has been rendered non-identifiable presents lower risks than linked identifiable or re-identifiable data; however, risks in relation to interpretation harms and re-identification remain, and researchers must consider them.
- 12.34 Researchers must respect any conditions concerning data-linking expressed within participants and/or individuals’ existing consent. In the absence of direct participant and/or individual consent, a [waiver](#) must be sought from an ethics committee.
- 12.35 The amount of data that is linked should be fit-for-purpose. Researchers must be able to justify re-use of requested data.
- 12.36 Researchers should be aware that if their research includes data linkage the methods by which that data was collected may result in systematic biases. This in turn may have implications for the validity of the research results.
 - 12.36.a Researchers should consider these limitations when designing their research and mitigate the impacts of these biases where possible. They should also be recognised when reporting research results.
- 12.37 Researchers should account for the destruction of any linked data. If an explicit destruction plan is not specified, then the rationale for archiving should be provided. Any long-term data storage must adhere to local data governance, national standards, and law as applicable.

- 12.37.a In considering how long to hold linked data, researchers must undertake a balancing exercise between the advantages of the robustness of data linkage and the ability to validate data linkage and protection of privacy, and benefits of re-use of data.
- 12.37.b Researchers should be prepared to provide local data governance committees (for example, a research office at a DHB) or ethics committees with a detailed plan of linked data storage, an accounting of the risks of storage, and plans to mitigate the risk of storage.
- 12.38 Researchers must work within established organisational governance structures, as well as develop specific data management plans that ensure the data is being accessed and linked in an appropriate and responsible manner.
- 12.39 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.
- 12.39.a 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 should take into account the potential uses and analysis of the data, which in turn affect data governance and management.

Databanks (registries)

The term 'databanks' in these Standards encompasses a wide range of data types and methodologies, from registries⁹² to databanks.⁹³

Databanks provide a major resource for many public health and epidemiological research activities, ranging from disease prevention to resource allocation. Researchers can use them to significantly accelerate understanding of health; diseases; and the effectiveness, efficiency, safety and quality of preventive, diagnostic and therapeutic interventions.

⁹² 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.

⁹³ 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. See further CIOMS and WHO 2016; WMA 2006; and NHMRC 2018, Chapter 3.2.

However, databanks raise issues of dignity, autonomy, privacy, confidentiality and discrimination. Researchers should address these issues in accordance with the following general principles.

- Research using databanks should benefit society, particularly in terms of public health objectives.
- Researchers have ethical and legal obligations to respect the dignity, autonomy, privacy and confidentiality of individuals when using data from databanks.

Government agencies may establish mandatory registries and databanks (e.g. the New Zealand Cancer Registry) in which participants and/or individuals are obliged to provide data rather than volunteering or consenting to do so. Research using such registries and databanks may be mandated (e.g. one of the purposes of the New Zealand Cancer Registry is to provide a basis for cancer survival studies and research programmes) and may not require ethical review or a waiver of consent.

However, for research studies that use identifiable or re-identifiable data from such databanks or registries and combine it with other data (e.g. data collected from participant and/or individuals via questionnaires), researchers must obtain participant and/or individuals' consent or if it is not practical to do so, seek a waiver of consent.

12.40 When planning to contact people because their data is included in a databank, researchers 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 such data.

12.41 Researchers must seek a waiver or obtain participant and/or individuals' consent to submit their data to databanks, paying particular attention to the parameters of consented **future uses**. Researchers must respect any conditions that participant and/or individuals have placed on the use of their data stored in databanks.

12.41.a In limited circumstances, researchers may use identifiable data stored in databanks **without consent**; in these circumstances, they must first justify such use to an ethics committee and receive approval.

12.42 Databanks must have a **governance** structure in place to protect the rights, dignity, autonomy, privacy and confidentiality of participant and/or individuals and their communities.

12.43 Researchers should make relevant information on the governance of databanks available to the public.

Governance, policy, and principles of databanks

12.44 Robust governance of databanks is important, to maintain the public's trust in research that uses data from them. Some databanks may have distributed governance arrangements, where different parties are responsible for different aspects of governance. A databank's governance structure, policy and principles must address:

- the purpose of the databank
- in broad terms, the types of research for which the databank may be used, and the types that are not permitted, or are permitted only after individuals have re-consented
- procedures for obtaining consent from participant and/or individuals for submitting data into the databank and using data stored in the databank, including the documentation of restrictions on **future uses** of participant and/or individuals' data, conditions on the identifiability of data, and other issues (e.g. intellectual property rights), to ensure they are traceable and respected
- criteria for determining when researchers may use participant and/or individuals' **data without consent**, and the procedures that they must follow in this case
- procedures for participant and/or individuals' withdrawal of consent, and circumstances under which it is not possible for participant and/or individuals to withdraw consent
- criteria for determining when participant and/or individuals need to be re-contacted, and procedures researchers must follow in this situation
- criteria for determining who may access and use participant and/or individuals' data and under what circumstances
- methods for ensuring researchers and others accessing and using participant and/or individuals' data will be held accountable for unauthorised access to, or inappropriate or unauthorised use of, participant and/or individuals' data
- measures for the physical and electronic protection of participant and/or individuals' data
- procedures for quality control of data collection
- procedures for research involving **data-linking**, including maintenance of the confidentiality of the link between collected data and personal identifiers
- mechanisms for keeping participant and/or individuals informed of research outcomes
- procedures for participatory engagement with patient groups or the wider community
- methods for ensuring the transparency of the databank's operations

- procedures for allowing participant and/or individuals to request corrections to mistakes and omissions of their data
- arrangements for the storage, disposal and destruction of participant and/or individuals' data (unless data is stored indefinitely, which requires an ethical justification)
- the person or people who are responsible for the governance of the databank
- arrangements for dealing with participant and/or individuals' data if the databank has a change of ownership or closes
- arrangements for protecting the privacy, rights and welfare of participant and/or individuals whose data is stored in the databank.
- procedures to be followed if a researcher is considering reconstructing pre-existing data into a format that suggests it will become a new databank (in this case, the researcher should attempt to identify custodians of the original data and seek advice about governance issues from these custodians)
- procedures for receiving and addressing enquiries and complaints.

13 Health

data and new technologies

Introduction

The increase of digital data collection and computational speed has facilitated the rapid development of analytical tools and techniques to gain additional insight from data. Statistical analysis, machine learning, and artificial intelligence are terms used to describe a spectrum of analytic techniques that range from traditional statistical analysis through to evolving approaches such as deep learning.

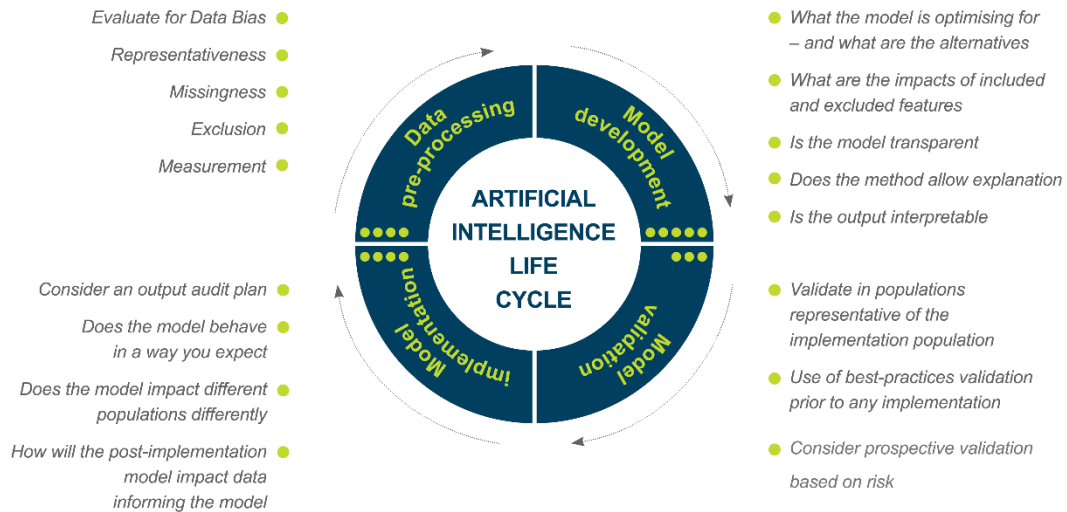
However, for the purposes of this document 'artificial intelligence' (AI) will be used to encompass approaches that are algorithmically-driven. This definition is intentionally broad as AI is often used as an umbrella term to refer to a number of techniques, encompassing everything from machine learning and natural language processing to expert systems and vision. In these Standards, the term 'AI' covers all these techniques.

AI is a rapidly evolving science, and the application of AI in healthcare has the potential to significantly transform healthcare delivery at all steps of the patient journey. Potential or realised applications would cover prediction of illness in the presently well individual through diagnosis to death, and will touch on all aspects of population health, system planning, service delivery, and individual medical specialities.

While offering great opportunity, these emerging technologies present defined and presently undefined risks, and the evolving science of AI presents difficulty in outlining explicit ethical standards. Therefore, this section will first frame the general principles guiding the ethics of biomedicine as they apply to AI, then frame standards applying these principles to specific circumstances. All researchers employing health data in AI systems throughout the AI life cycle as outlined in Figure 13.1 should refer to the ethical principles described below in the absence of a standard that directly applies to their case. The standards in this chapter are also likely to be updated periodically.

Researchers are encouraged to check for updates prior to submitting applications which involve the use of AI for ethical review.

Figure 13.1 – The AI life cycle



An AI project can be broken down into series of interdependent steps:

- **data pre-processing** is the is the curation and refining of raw data into a data set that can be utilized in subsequent model development. This step can be automated or human determined.
- **model development** is the selection of specific methods to analyse the data, decisions made to train the underlying statistical model, and selection of model parameters and hyperparameters.
- **model validation** is the process of determining the model performance in a data set different from the data set in which the model was trained. This can be done retrospectively or in a prospective population.
- **model implementation** is the application of the validated model into a live environment, where the output of the model impacts something outside the model itself. This is the highest risk step in the AI life cycle

Not all AI projects will touch on all elements of this life cycle.

Ethical principles in the context of AI

Given the breadth of situations to which AI is being applied, the emerging use of AI systems in healthcare raises a number of potential ethical challenges. Other jurisdictions have highlighted that AI interfaces with the themes of consent, autonomy, privacy, fairness, bias, justice, transparency, reliability, accountability and liability (Nuffield Council on Bioethics 2018; Fenech et al 2018). As healthcare systems and healthcare delivery increasingly

become supported by, integrated with, or delegated to AI systems it is critical that they are in line with the fundamental societal values that shape healthcare delivery and research ethics as well as individual rights. Ethical reflection about AI should be grounded on the ethical principles and concepts applicable to health data generally.

Certain aspects of AI development create unique difficulties in foreseeing the impact of the technology on some of these principles. The concepts around algorithmic transparency, interpretability, and explainability are presently evolving – leading to so-called ‘black-box’ problems, where the impact of any specific data structure or element on the final algorithmic output is obscured by the methodology itself. The above principles can still be applied in this circumstance, but may not be applicable by design, only by transparency of the impact of AI implementation in the broader biomedical and societal context.

- 13.1 While the state of AI does not guarantee built-in explainability, researchers must ensure that the processes, capabilities, purpose, and impact must be transparent and evaluable.

Use of data

Data is used to develop the algorithms supporting AI, and in self-learning approaches is used in implementation. This data may be from traditional healthcare domains, such as clinical activities in healthcare environments, data generated explicitly or as a by-product of screening, diagnosis, and treatment. This may include demographics, medical notes, electronic recordings from medical devices, data from physical examinations and clinical laboratory data, imaging and genetic testing (Jiang et al. 2017). AI systems may merge these health data sources with non-health data, such as social media, locational data, and socio-economic data.

- 13.2 While individual datasets may be non-identifiable, as data sets are merged, AI researchers should be conscious that methodologies presently allow identification of even non-identified data contributors if the dataset is sufficiently linked with a high degree of accuracy.
- 13.3 Researchers of AI need to carefully consider the nature of the data, as well as the people who are accessing and using the data.

Risk considerations of AI outputs

- 13.4 Researchers must carefully consider the risk of harm the use of AI may cause to participants.

A useful framework for risk categorisation has been developed by the International Medical Device Regulators Forum (IMDRF) for **Software used as a Medical Device (SaMD)**. According to the SaMD risk framework, consideration should be given to the following two major factors which help to describe the intended use of the AI which, in turn, helps to inform the risk its outputs may have on participants:

- 1 The significance of the information provided by the AI and whether it is to:
 - treat or to diagnose;
 - drive clinical management; or
 - inform clinical management.

- 2 The state of the situation or condition for which the AI is intended to be used, namely, is it intended to be used in a:
 - critical situation or condition;
 - serious situation or condition; or
 - non-serious situation or condition⁹⁴

Table 13. 1 – Risk matrix

| State of healthcare situation or condition | Significance of information provided by SaMD to healthcare decision | | |
|--|---|---------------------------|----------------------------|
| | Treat or diagnose | Drive clinical management | Inform clinical management |
| Critical | IV | III | II |
| Serious | III | II | I |
| Non-serious | II | I | I |

After determining the significance of (1) the information provided by the AI to the healthcare decision, and (2) the state of the healthcare situation or condition for which the AI is intended to be used, Table 13. 1 SaMD risk matrix provides guidance on the levels of impact the AI may have on participants.

The four categories (I, II, III, IV) are in relative significance to each other; Category IV has the highest level of impact while Category I has the lowest impact.⁹⁵

⁹⁴ Further descriptions and examples of these decisions, situations and conditions may be found at: <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf>

⁹⁵ Further explanations of this matrix may be found at: <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf>

General considerations

These standards apply to data used for pre-processing, model development and validation and implementation of AI.

- 13.5 Researchers must ensure that the intended use of AI is fair and is intended to benefit New Zealanders (Stats NZ and Privacy Commissioner 2018). They must identify the risks and benefits of the AI system, paying particular attention to ensuring it does not contribute to inequalities, for example by negatively discriminating against classes of individuals or groups.
- 13.6 Researchers must be mindful of the need to consult with Māori as partners, and of the need to consult with all relevant researchers to ensure they manage data use involving AI systems in a trustworthy, inclusive and protected way (Stats NZ and Privacy Commissioner 2018).
 - 13.6.a **Consultation** is especially important if the research is a partnership between private and public organisations. In this case, researchers must clearly identify the aims and goals of each contributing partner, together with information about who will have access to what data and for what purposes, and who is accountable.
- 13.7 Intended use of AI should be explained in language that is clear, simple and easy to understand to those not directly involved in the AI lifecycle.
- 13.8 The source of the data, particularly with regards to quality, completeness, representativeness, and risk of bias, should be evaluated.
 - 13.8.a Design and the implementation of measures to correct and mitigate risks arising from data bias should be considered.
- 13.9 The data should be evaluated with regards to identifiability and risk of re-identification.
- 13.10 Data used in an AI life cycle must be safeguarded with both data security and integration of appropriate levels of security into data storage and each element of the AI life cycle, including against adversarial attacks.
- 13.11 Data used in AI should have a plan for storage, reuse, destruction or retention, and should have **effective and robust data management plans in place**.
- 13.12 Project-specific data governance policies and procedures should adhere to local, organisational, regional, and national data governance requirements.

Transparency, explainability, and interpretability

- 13.13 Researchers must be transparent about methodologies used in the AI life cycle. There should be justification for a specific method, an accounting for the specific risks and limitations of the methodology, and the consideration of alternative approaches.
- 13.14 Model development and choices of methodology should be clear in their optimisation parameters and explainability of input and output to model.
- 13.15 AI implemented in live environments are strongly encouraged to have a monitoring and audit plan in place to assess issues of safety, accuracy, bias and fairness.
- 13.15.a Insight into the drivers of AI output is at times limited by the methodology itself – concepts such as black-box algorithms, explainability, and transparency are set against issues such as fairness and bias. However, such approaches do not remove ethical accountability from the researchers. Current approaches to accessing and evaluating risk in this setting recommend ongoing audit of input and output.
- 13.15.b Measures to mitigate risks arising in safety, accuracy, bias and fairness resulting from the application of AI should be in place prior to implementation.
- 13.15.c Algorithms should be transparent about the involvement of automated input-output loops versus human-in-the-loop designs. Provision for human input and oversight should be integrated into design or implementation governance structures. If there is no such provision, this absence must be justified.

Human oversight and accountability

- 13.16 Researchers must clearly identify who is accountable for each step of the AI life cycle, and how they are accountable.
- 13.16.a Accountability in this context references both accountability for algorithmic behaviour/output, and accountability for subsequent actions based on the algorithm. Clear lines of accountability for addressing safety, accuracy, bias and fairness involving the AI should be in place prior to any deployment/implementation.
- Organisations involved in an AI lifecycle should have clear lines of responsibility for each step of the AI life cycle.

- AI in a public-private partnership should have clear delineation of responsibility between the partners.

Standards for an AI life cycle

13.17 Prior to data pre-processing, model development and validation, researchers using AI should account for the following:

- the source of the data to be used by the AI system (e.g. clinical notes, imaging, genetics or laboratory results)
- attention should be paid to issues of bias (having particular regard to the quality, completeness and representativeness of the data),
- a clear description of methodology/methodologies to be used in the project. A justification for the method/methods, limitations, risks, and optimisation parameters should be presented.
- an explanation of how the data will be pre-processed and why, and an identification of any protected attributes
- the identifiability of the data (i.e. identifiable, re-identifiable or non-identifiable) and, if the data is re-identifiable, a description of the risks of re-identification, and of the measures used to mitigate those risks
- measures the researchers will take to mitigate risks identified, especially in terms of correcting bias
- an explanation of how the researchers will determine accountability for safety, accuracy, bias and fairness issues
- a description of how the AI system will be validated.

13.18 Prior to implementation, researchers using AI should account for the following:

- an explanation of how the proposed use will be monitored for safety, accuracy, bias and fairness, including measures used to assess and why those measures have been selected, paying particular regard to whether certain groups would be advantaged or disadvantaged by the method(s)
- a plan for ongoing audit in implementation. This is particularly relevant for settings where algorithmic updating is dependent upon data created by the implementation
- there should be a list of the people and organisations involved in the AI life cycle, including their qualifications
- an audit and monitoring plan for the AI to assess issues like safety, accuracy, bias and fairness; how often the auditing and monitoring will take place; and who will be responsible for it

- an explanation of how the researchers will determine accountability for safety, accuracy, bias and fairness issues
- a statement as to whether there will be human oversight of the AI system, and, if so, what the oversight comprises, the stages at which it will occur and how the oversight will be implemented.

14 Human tissue

Introduction

Human tissue is commonly used in health research. Its use is increasing as the cost of new technologies decreases. 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. Blood serum is acellular and not considered a material subject to the Human Tissue Act 2008.

For legal purposes, human tissue is defined in section 7 of the [Human Tissue Act 2008](#).

14.1 For the ethical considerations for using tissue in future unspecified research, see [Consent for future use of health data and human tissue](#).

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 or communities.

Some groups hold beliefs about the sacred or shared value of human tissue; researchers should respect these beliefs.

When research involves Māori tissue

Researchers should consider the following in research on human tissue.

- The traditional Māori view is that tissue is a taonga – tissue itself and any associated data are of value, and should be appropriately managed.
- Protecting whakapapa must be a key concern; this involves protecting the connection between tissue and the person from whom it originated, as well as the family and whanau.
- In the Māori view, provision of tissue may be seen as a tākoha – a form of gifting whereby there is tapu associated with the gift, and certain conditions therefore apply.

- Given the range of views among Māori, researchers may need to consult beyond the family and whānau; that is, they may need to consult the wider community or iwi (Hudson et al 2016b).

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 research is a culturally informed activity.

Researchers must consider the ethical issues related to collecting and using human tissue alongside the ethical issues related to the [information](#) derived from the tissue.

The use of stem cells in research is considered as a special case of tissue use. 'Research with stem cells and reprogrammed cells', contains separate Standards for this area.

Use of tissue

- 14.2 Researchers must treat samples of human tissue as tākoha (donations or gifts). They must conduct research involving these samples with respect and transparency.
- 14.3 Researchers should use existing tissue in an ethical manner, and in accordance with the terms of the original gift or consent.
 - 14.3.a Where possible, researchers should give preference to existing sources of tissue, if these fulfil their scientific goals, rather than collecting new samples.
- 14.4 Researchers must not retain samples of tissue 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 them.
- 14.5 Researchers must have a clear strategy in place for managing health-related findings (expected or incidental) from tissue analysis.
- 14.6 Those who collect, use and store the tissue must be suitably qualified⁹⁶ or experienced (or supervised by those who are).
- 14.7 Access to tissue obtained for a study must be restricted to those who need it to undertake the study.

⁹⁶ For example, performing a muscle biopsy is a 'Restricted Procedure' under the Health Practitioners Competence Assurance Act 2003 and the Health Practitioners Competence Assurance (Restricted Activities) Order 2005.

Consent and waivers

- 14.8 Researchers must get **informed consent** from the person from whom the tissue was or will be collected before they use it for research, unless;
- 14.8.a consent from a family member has been provided in the case of a person being deceased or
- 14.8.b a **waiver** of consent is approved by an ethics committee.
- 14.9 Gaining informed consent to use tissue in research should always be the default starting point. Where researchers propose to use tissue without specific consent for research (e.g. where tissue was collected for clinical investigation, or the proposed 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.
- 14.10 Researchers should carefully consider whether they should undertake robust, active and ongoing engagement with relevant communities and stakeholders to establish whether the proposed tissue use is acceptable.
- 14.10.a Any such **engagement** should be transparent and fair, done in good faith and be truthful, consistent with the concepts and practice of whakapono and whakataukī.
- 14.11 When considering a waiver, researchers should identify if there is any known or likely reason to expect that the participant(s) would not have consented if they had been asked. For example, are there elements which would be upsetting to the people who the tissue belongs? This is not something for researchers to prove beyond reasonable doubt, but the researcher needs to consider this aspect of use of tissue without consent.
- 14.12 When research involves using clinical samples, researchers' use of tissue must not compromise the primary clinical reason for collecting the tissue.
- 14.13 Researchers must maintain participants' privacy and confidentiality throughout the period during which they are using and storing the tissue and its associated data.

- 14.14 Researchers must consider the potential psychological, social and cultural significance of their use of tissue, and plan to minimise all research harms.
- 14.15 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
 - managing privacy and confidentiality
 - returning results appropriately and [managing incidental findings](#)
 - giving special consideration to the issues involved in exporting or importing tissue.

Management plans

- 14.16 When undertaking research involving human tissue, researchers must prepare and follow a tissue management plan that clearly describes the specific purpose of the tissue collection and how the researcher intends to process, store, distribute, use and dispose of the collected tissue.
- 14.17 The tissue management plan should be contained in either the study protocol or laboratory manual, and should specify:
- the methods of collection to be used, volume of tissue to be collected and schedule of collection
 - measures taken to de-identify tissue samples and maintain privacy and confidentiality
 - methods, location and duration of storage
 - planned analyses
 - access to tissue during the study
 - what will happen to the tissue after the study is completed, including details of ongoing storage, whether other researchers will have access to the tissue or be able to distribute it, and whether it will be returned to donors
 - the method of disposal.
- 14.18 Researchers must communicate the contents of the tissue management plan to participants in plain, non-specialist language as part of the process of obtaining their fully informed consent.

Identifiability of tissue

In the context of advances in genetic analysis and data-linking, and the prevalence of biobanks that contain identifiable tissue, researchers should always see human tissue samples, in principle, as re-identifiable. However, levels of identifiability do not affect the ethical implications of using tissue in research.

- 14.19 Researchers should remove unnecessary identifiers associated with human tissue samples before storage and analysis, to reduce the risk of confidentiality breaches.
- 14.20 Where identifiers on human tissue are necessary (for instance, where researchers test tissue samples provided in clinical trials and report on them for a purpose that is fed back to the clinical team and in some way determines or directs the treatment of participants), researchers should include this fact in the information they give to participants as part of the process of obtaining their informed consent.

Import and export of human tissue

- 14.21 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.
- 14.21.a Local iwi and or local research institutions may have different views on exporting tissue; researchers should consult them early to obtain those views.
- 14.22 When considering the import of tissue from another country for use in research in New Zealand, researchers should attempt to establish whether the tissue was obtained in a manner consistent with these Standards. If they cannot, they should not use the tissue for research in New Zealand.

Incidental findings

- 14.23 Standards under '[Returning results and incidental findings](#)' apply to incidental findings in the context of the use of human tissue. 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](#).
- 14.24 Researchers have a duty and responsibility to inform participants, and ensure adequate follow-up is in place after providing feedback on results or incidental

findings. In some research situations it may only be ethical to return clinically significant or clinically actionable individual results.

- 14.25 Confirming if follow-up is appropriate may involve a referral to a suitable health professional or specialist. Suitable counselling (clinical, genetic or emotional) may be necessary for participants, depending on the information uncovered. The study protocol should detail these plans.
- 14.26 Researchers should also consider whether any study results relating to human tissue may have direct implications for the health of a participant's family, especially in the case of genetics research.

Genetic research

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.

Researchers are increasingly studying genes and genetic information in clinical, epidemiological and social research, as well as in basic research.⁹⁷ 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. These Standards are in addition to the Standards on the use of [human tissue](#).

Genetic research needs careful and specific ethical consideration, because it may reveal information about the predispositions to disease of both an individual and their family. Whether or not the disease develops in the individual, information arising from research may have implications for people's access to employment and education, and to benefits or services, including financial services such as banking, insurance and

⁹⁷ Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view.

superannuation. The information may also have important implications for blood relatives and family.

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.

Genetic research involves risks that the information arising from genetic research may be misrepresented or misused in ways that lead to prejudice, stigma, disrespect, discrimination or other harms to participants, their families and communities.

- 14.27 In designing, conducting and reporting genetic research, researchers must consider the potential psychological, social and cultural significance of their research, plan how to minimise harms, and provide full information about the risks to prospective participants.
- 14.28 Researchers must consider the potential psychological, social and cultural significance of their research and plan to minimise all research harms.
- 14.29 Researchers must prepare and follow a detailed plan for generating and using genetic material and information.
- 14.30 Researchers should inform relevant clinicians or seek further advice if clinical action is possible in response to the genetic information they discover, if participants consent to this.
- 14.31 Researchers must inform participants whether their research might generate information that the participant may be legally required to disclose to a third party (e.g. for the purposes of insurance, employment, finance or education).
- 14.32 Researchers must not use or release genetic material and data for purposes unrelated to their specific research without participants' consent, unless they are required to by law.
- 14.33 If their research involves participants' family members, researchers must consider whether those family members are themselves participants, and whether it is therefore appropriate to seek their informed consent.
- 14.34 Unless required to fulfil primary study objectives, donation of tissue for broad genetic testing (such as whole genome sequencing) should be optional for participants.

- 14.34.a Studies that require mandatory broad genetic testing for research outside the main study may result in under-representation of Maori and other groups.

Genomic research

Genomic research is research with the potential for hereditary implications (effects on other family members) which may range from single-gene genetic research to whole genome sequencing and other '-omic' research (e.g. exomic or proteomic research) with potential hereditary implications.

- 14.35 Researchers undertaking genomic research involving identifiable hapū, iwi or Māori communities should consult with collective groups early in the research planning phase, and throughout it (Hudson et al 2016b).
- 14.36 Genomic research involving Pacific people or communities should comply with the HRC's *Pacific Health Research Guidelines* (HRC 2014b).

Incidental genetic results

Research results, genetic material and information collected for genetic research may be significant for research participants, their blood relatives and families. It may interest family members who are not blood relatives (e.g. partners and spouses, who have an interest in the health of their children). Research may have complex and socially significant implications for communities. It may potentially inform people's life decisions, including health decisions.

Genetic research can reveal information about previously unknown paternity or maternity. It has uses outside health, such as for tracing migration patterns and in studies of cultural relatedness.

However, researchers must acknowledge that some people may prefer not to receive information arising from genetic research, or even to know of its existence.

- 14.37 Where research generates information of potential importance to the future health of participants 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:

- 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 re-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 special provisions in place to protect the privacy and confidentiality of genetic information
- record any circumstances under which participants may be statutorily or contractually obliged to disclose the results of genetic tests or analysis to third parties (e.g. insurance companies, employers or financial and educational institutions)
- detail any restrictions in place on the release of stored data or material, especially in the context of studies of rare genetic disorders, where it may be possible to identify individuals, families or members of a community even if information is given to others in non-identifiable form.

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

14.39 Before seeking their consent to genetic research, researchers must inform participants:

- 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 may receive the material or information
- whether information from or about their family members, in addition to that provided by participants, is required for the research
- whether, if a participant consents to researchers approaching their relatives, the participant has the opportunity to make initial contact with those relatives
- 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 that 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 concerned, with the approval of a health and disability ethics committee, even if the participant does not consent to this disclosure

14.40 Advice researchers provide to participants about the results of genetic research needs to include a clear explanation of the difference between research and clinical testing, and to clarify the potential need for clinical testing of research results. The research design could include a plan of how researchers will handle this situation. 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
- access to, or a recommendation to seek, advice or counselling about the possible implications of the information.

14.41 In research studying large numbers of genes simultaneously, participants may not be informed of all of the names of all the individual genes to be studied.

Gene editing

Gene editing is a group of technologies that give scientists the ability to change an organism's DNA. These technologies allow genetic material to be added, removed, or altered at particular locations in the genome. Because gene editing is a frontier science, these Standards focus on principles for respecting, protecting and promoting the health and wellbeing of individuals, whānau and communities; guarding against unwanted societal effects; and equitably distributing information, burdens and benefits.

The ethical and regulatory issues surrounding the use of gene editing for therapeutic purposes are not very different from those associated with any experimental therapies. Patient safety is a crucial consideration; researchers can address this through improved techniques, procedural guidelines as to appropriate risk and patient consent processes.

14.42 Gene editing research should aim to promote the health and wellbeing of individuals, such as by treating or preventing disease.

- 14.43 Gene editing research must comply with relevant legislation and guidelines, including:
- the Hazardous Substances and New Organisms Act 1996
 - the Human Assisted Reproductive Technology Act 2004
 - the Royal Society's Code of Professional Standards and Ethics in science, technology and the humanities.
- 14.44 Clinical trials that involve the use of a new or unregistered medicine require approval from the Standing Committee on Therapeutic Trials (SCOTT).
- 14.45 Scientific assessment of clinical trials that involve the introduction of nucleic acids, genetically manipulated micro-organisms, or viruses or cells into human subjects must have approval from the HRC's Gene Technology Advisory Committee (GTAC).
- 14.46 No gene editing or research may be performed on viable human embryos.
- 14.47 Gene editing research must be approved by the Environmental Risk Management Authority (ERMA) and comply with ERMA regulations
- 14.48 Researchers must obtain informed consent for the future use of tissue separately from informed consent for clinical treatment.
- 14.49 All researchers conducting gene editing research must be respectful to other people, to this end they must act with cultural intelligence and intellectual rigour (pūkenga), and respect diverse values and communities (under the Te Ara Tika principle of [manaakitanga](#)).
- 14.50 Researchers must recognise the personal dignity of all individuals, acknowledge the centrality of personal choice and respect individual decisions.
- 14.51 Under the [Te Ara Tika principles](#), all gene editing research should endeavour to identify and engage with affected communities (whakapapa), recognise their rights (mana) and respect their interests (tika).
- 14.52 Researchers must manage collected data responsibly.
- 14.53 All gene editing research should recognise the potential impacts of the research on communities, including in an intergenerational sense.
- 14.54 Researchers undertaking research involving the development of genetically edited cells for clinical use must be able to scientifically justify that research. Such research must be conducted (and peer reviewed) by individuals with appropriate expertise and training.

- 14.55 Where applicable, researchers should recruit participants for clinical gene editing research from populations that can benefit from the results of this research.
- 14.56 Where gene editing techniques are proven to have a therapeutic benefit, researchers should widely distribute this information to the appropriate research community in a timely manner, to foster equitable access to the benefits of the resulting clinical applications.

15 Biobanks

Introduction

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; and
- associated demographic and health information.

Some common features of biobanks are as follows.

- They are ongoing and open-ended, which allows for unspecified future research and the donation of tissue that is stored for definite or indefinite periods
- They need tissue and data to remain potentially re-identifiable, even if they are coded, because researchers may need to link tissue and associated data to other sources of health information for studies in the future, or to follow up information added over time
- They focus on the common good, with a greater concern for future public benefit than individual benefit for participants themselves. Currently, many studies that make use of biobanks offer no direct or immediate benefit to individual donors.

In te ao Māori, the donation of a bio sample is a “tākoha”. The gift of the donation refers to the responsibility to look after the taonga. Kawa (principles) should be considered at every decision-making point to ensure that responsibility towards tikanga (custom) is being met during at all points during each step involving the donation

In most situations, the custodian of human 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 a biobank stores coded tissue, it may appoint a custodian independent of both the tissue collectors and the researchers to maintain the tissue in coded form while enabling individual participants to access their own identified results or tissue.

General considerations

- 15.1 Researchers obtaining tissue samples for a biobank should collect and store tissue and make it accessible in such a way future research can make use of it.
- 15.2 Researchers should record restrictions on the use of participants' tissue and make them known to other researchers who wish to access the biobank for their own studies.
- 15.3 Researchers and custodians of biobanks should observe confidentiality agreements with participant about stored tissue. Custodians should take every precaution to prevent the tissue from becoming available for uses to which participants did not consent.
- 15.4 Researchers and custodians of biobanks must ensure that the biobank is used responsibly and respectfully, and that the privacy of participants is safeguarded.
- 15.5 Researchers and custodians of biobanks should consider denying or restricting access to some or all of the biobank samples for uses that could harm participants.
- 15.6 Researchers must justify any collection, use or retention of tissue beyond what they require for a particular study, and must gain separate consent for such activities, or in limited circumstances seek a waiver.
- 15.7 When a biobank is closed, researchers should appropriately transfer or dispose of the biological material and data.

Informed consent

- 15.8 When seeking participants' consent for storing tissue in a biobank, researchers should provide information on:
 - the purpose of the biobank
 - 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 the transfer of tissue or material to other institutions or countries
 - the risks and burdens associated with collecting, storing and using tissue
 - the nature of the tissue they will collect
 - the form (i.e. identifiable, re-identifiable or non-identifiable) in which they will store the tissue

- whether the researcher and/or custodian of the biobank will seek specific or broad 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
 - what will occur if the biobank management changes.
- 15.9 Researchers must inform participants that if the tissue is made non-identifiable, they may not be able to know what is done with their tissue, and in this situation they will not have the option of withdrawing their consent. Researchers should be aware of the following aspects in regard to unspecified consent.
- A participant's unspecified consent may sometimes need to include permission to enter tissue into a biobank.
 - 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 a participant's original or unspecified consent. In this case, they must seek consent to access the additional tissue.
- 15.10 Researchers' use of biobanks must comply with conditions that the providers of the tissue have specified.

Limitations of consent

In the context of biobanks, due to the prevalence of future unspecified research, consent does not protect all the interests of participants. Neither does it set aside the moral duty of care that researchers who can access a biobank owe to participants.

- 15.11 Researchers need to establish a coherent set of measures for protecting the interests of participants in addition to consent procedures, such as removing identifiers on data and adhering to the forms of governance that guide the conduct of professionals in the public interest.
- 15.12 Researchers should establish these measures in relation to 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

15.13 Researchers or custodians of biobanks 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.

15.14 In this case, governance arrangements should cover:

- the purpose of the biobank
- how the biobank will be used
- the form (i.e. identifiable, re-identifiable or non-identifiable) in which the tissue will be stored
- the rules of access to the biobank
- how researchers or custodians will protect privacy and confidentiality of participants
- 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's operation transparent
- ways in which researchers will be accountable for complying with requirements addressing access, use and privacy.

15.15 Researchers or custodians of biobanks must involve a range of people with relevant interests when they are developing governance arrangements, in the ongoing management of the biobank and in the periodic review of governance arrangements.

15.16 In developing governance arrangements, researchers or custodians of biobanks should:

- identify potentially relevant values and interests
- take special care to identify people whose interests may be especially at risk, and interests that arise from diverse values
- identify existing privacy norms in relation to contemplated uses

15.16.a When people with relevant interests participate in the design and governance of biobanks, researchers can identify relevant privacy norms and develop governance measures (e.g. design of consent and authorisation measures) in relation to these norms.

Transparency

- 15.17 Participants have the right to request and receive information from biobanks about their stored tissue and how it is being used.
- 15.18 Participants have the right to request that researchers correct mistakes or omissions about their health data.
- 15.19 Certain information held by biobanks should be publicly available. This includes information on:
- who may have access to tissue and other information, and for what purpose
 - tissue-sharing agreements
 - if relevant, the results of independent audits of compliance.
- 15.20 Researchers or custodians of biobanks must keep an auditable record of all researchers who receive access to the biobank, and the purposes of that access.
- 15.21 Researchers or custodians of biobanks must report any privacy breach affecting a participant to that participant.

Public interests and privacy interests

The public has an interest in the responsible use of tissue to improve the 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.

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; for example, using their tissue for research and publishing the results in an identifiable way.

Misuse of tissue can harm individuals, groups and communities. Such harm may include loss of privacy, stigmatisation, discrimination or financial loss.

- 15.22 The broader public interest may come into conflict with individual privacy. Researchers or custodians of biobanks should seek to avoid potential conflicts and violations rather than addressing them retrospectively.

Using identifiable tissue for accurate linkage

- 15.23 It may be permissible for a researcher to use identifiable tissue to ensure a linkage is accurate, even if participants have not given their consent for the use of the identifiable tissue. In this case, researchers must assure participants that they will not disclose their identity for purposes beyond this use. When linkage is complete, researchers must remove identifiers from tissue unless participants have consented to its use in an identifiable form.
- 15.24 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 providing the linked tissue to the researchers.

Transferring existing samples of tissue when a donor is deceased

- 15.25 If tissue is to be stored or used for a purpose other than research (e.g. continued storage in a biobank, unrelated to a particular research project), researchers or custodians must meet the informed consent conditions set out in section 31 of the [Human Tissue Act 2008](#):
- (1) This section applies to informed consent to collection or use, for any purpose that is not anatomical examination, public display, or both, of human tissue that is, or is collected from, a body.
 - (2) Informed consent to which this section applies may only be given by the following people in the following circumstances:
 - (a) the individual whose body is the tissue, or from whose body the tissue concerned is collected, and before his or her death:
 - (b) that individual's nominee or nominees, on behalf of that individual and after his or her death, if–
 - (i) no consent has been given under paragraph (a); and
 - (ii) no informed objection has been raised by that individual:
 - (c) a member of that individual's immediate family and on its behalf after that individual's death, if–
 - (i) no consent has been given under paragraph (b); and
 - (ii) no informed objection has been raised by that individual's nominee or nominees:
 - (d) a close available relative of that individual after his or her death, if–
 - (i) no consent has been given under paragraph (c); and
 - (ii) no informed objection has been raised on behalf of that individual's immediate family.

16 Research with stem cells and reprogrammed cells

Introduction

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 on research with stem cells. Human stem cells are characterised by their capacity for self-renewal and their ability to differentiate into different types of cells under the right conditions. Stem cells can be divided into a number of broad categories, each of which have different ethical considerations.

These categories include:

- tissue-derived stem cells
- embryonic stem cells, and
- induced pluripotent stem cells.

Stem cell research has two broad arms: 1) clinical interventions whereby stem cells are administered to patients, and 2) scientific investigations whereby the biology of stem cells is studied in various ways but the cells are not administered to patients. These Standards recognise that the risks associated with the two arms are very different. They set out special considerations about collecting and using stem cells, 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. They also distinguish the future use of stem cells from protocol-specific research, especially the requirements for separate consent.

Research with stem cells, stem cell lines and foetal tissue are subject to specific legislation and national guidelines, including:

- [Human Tissue Act 2008](#) – in terms of the collecting, storing and disposing of stem cells (although section 7 of the Act states that cell lines are not tissue, section 74 provides for regulations for their use in research)
- *He Tangata Kei Tua: Guidelines for Biobanking with Māori* (Hudson et al 2016a)
- *Te Ara Tika: Guidelines for Māori Research Ethics* (Hudson et al 2010)

- *Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research* (Ministry of Health 2006)
- the International Society for Stem Cell Research's *Guidelines for Stem Cell Research and Clinical Translation* (ISSCR 2016).

Use of stem cells in scientific non-clinical research

The risks involved in the use of stem cells for non-clinical research are much lower than the risks for the use of stem cells in clinical research.

- 16.1 Researchers should seek approval from an ethics committee for all research involving the isolation and derivation of stem cells or cells that will be used for reprogramming, and undertake such research only following written informed consent.
- 16.2 In some exceptional situations, consent for such research may be impossible or impracticable to obtain. In this case, researchers may only conduct the research after an ethics committee has considered and approved it.

Use of stem cells in clinical research

- 16.3 All research involving the clinical application of stem cells or reprogrammed cells must be subject to prospective ethical review, approval and ongoing monitoring by an independent ethics committee and registration with a recognised clinical trials registry. Such research must also be monitored by a data safety monitoring committee.
- 16.4 All researchers intending to conduct research involving the clinical application of stem cells or reprogrammed cells must demonstrate an appropriate level of quality control in the production of the cells, including in terms of the purity of the cells and the absence of oncogenic potential.⁹⁸
- 16.5 Researchers creating a stem cell line or reprogrammed cell line for clinical use must obtain informed consent for the future use of the tissue separately from informed consent for clinical treatment.
- 16.6 Research involving the development of stem cells or reprogrammed cells for clinical use must be scientifically justified. It must be conducted (and peer reviewed) by individuals with appropriate expertise.

⁹⁸ An oncogene is a gene that has the potential to cause cancer.

- 16.7 For products derived from totipotent or pluripotent stem cells, researchers must plan to minimise the persistence of any remaining undifferentiated cells, and demonstrate that these cells do not result in tumours in long-term animal studies, where appropriate (ISSCR 2016).
- 16.8 The appropriate therapeutic committee (typically SCOTT or GTAC) must review preclinical data and the trial protocols of research involving stem cells or reprogrammed cells.
- 16.9 Before any research employing stem cells or reprogrammed cells for therapeutic use begins, researchers must establish the specific risks and benefits associated with the particular type of cell research. In addition, they must adopt practices that address long-term risks associated with the procedures.
- 16.10 Where applicable, an intervention employing stem cells or reprogrammed cells must aim at being clinically competitive with or superior to existing therapies, or meet a unique therapeutic demand, or provide unique therapeutic outcomes.
- 16.11 Where applicable, researchers should recruit participants in clinical stem cell or reprogrammed cell research from populations that can benefit from the results of the research.
- 16.12 Early-phase clinical trials in which there will be an intervention involving stem cells or reprogrammed cells may enrol research participants who have run out of standard treatment options.
- 16.13 Researchers must not require participants to pay to participate in studies about stem cells.
- 16.14 Where research proves that stem cells or their derivatives have therapeutic benefit, researchers should disseminate this information as widely as possible.
- 16.15 Research employing stem cells or reprogrammed cells for clinical or therapeutic use may be associated with specific risks (such as cell contamination). Researchers must consider these risks in advance of their research, and address them in their protocols.
- 16.16 As stem cell or reprogrammed cell research may use identifiable human material or data (such as data contained in biobanks or similar repositories), researchers must seek informed consent for collecting, storing and reusing it. In some exceptional situations, consent for such research may be impossible or impracticable to obtain (e.g. in the case of cells obtained from a cell repository such as the American Type Culture Collection). In such situations, researchers may only conduct the research after a research ethics committee has considered and approved it.

- 16.17 Consent procedures for stem cell-based or reprogrammed 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.
- 16.18 Researchers should distinguish the protocol-specific intentions of their research from any future use of the material or data, and obtain separate consent for each of these activities.
- 16.19 When a clinical trial involves human research participants with less advanced disease, or when researchers anticipate using invasive delivery approaches (for example, the intramyocardial method) for stem cells or reprogrammed cells, researchers must follow stringent design and reporting standards.
- 16.20 All stem cell research must only be conducted by people with appropriate expertise and/or training. Relevant expertise includes previous experience with tissue culture techniques, embryo culture and stem-cell derivation in animal systems, and competence in the culture and maintenance of cell lines.

Human embryos and embryonic stem cells

In 2006, the Ministry of Health released *Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research* (Ministry of Health 2006). These guidelines provide health and disability ethics committees with an ethical framework for assessing applications to use established human embryonic stem cell (hESC) lines.

The International Society for Stem Cell Research's *Guidelines for Stem Cell Research and Clinical Translation* (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.

- 16.21 In the New Zealand context, the [Human Assisted Reproductive Technology Act 2004](#) provides specific legislation relating to research on non-viable 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.

Embryonic stem cells

Under the Ministry of Health's 2006 guidelines, researchers are able to use cells from established hESC lines with ethical approval.

Once established, hESCs are not embryos, and their use does not require the same level or type of regulation.

- 16.22 When considering research projects with hESCs, 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. Their study proposal should discuss alternative methods (if available), and provide a rationale for using the requested human materials. This rationale must include a justification for the derivation or use of hESC, for the proposed methodology and for performing the experiments in a human rather than animal model system.
- 16.23 All research involving hESCs must comply with relevant documents and legislation, namely, the *Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research* (Ministry of Health 2006), the [Human Tissue Act 2008](#) and the relevant guidelines of the Advisory Committee on Assisted Reproductive Technology.
- 16.24 The genetic modification or import of genetically modified human cells, tissues, gametes or embryos grown outside of the human body requires an approval from ERMA. Where researchers plan to import a cell line into New Zealand for the purpose of using established hESCs involving genetic modification must receive approval from ERMA, in addition to any other approvals required, before the cell line can be imported into New Zealand.⁹⁹
- 16.25 Researchers wanting to use New Zealand-derived embryos to create genetically modified hESC lines need to seek approval from both ECART and ERMA. If these hESC lines are to be used in clinical research or therapy (non-reproductive), the researcher also needs to seek approval from a health and disability ethics committee.
- 16.26 All research that involves totipotent or pluripotent cells derived from the inner cell mass of pre-implantation stages of human development, human embryos or embryo-derived cells is subject to ethical review, approval and ongoing monitoring by ECART. It must address the uniquely sensitive elements of hESC research.

⁹⁹ Since 30 October 2003, the genetic modification of human cells (but not human beings) has been classed as 'new organisms' under the Hazardous Substances and New Organisms Act 1996.

17 Compensation for injury in commercially sponsored intervention studies

Introduction

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. Participants who suffer a personal injury in a clinical trial may be eligible for treatment injury cover only under two conditions.

The two conditions are:

- an ethics committee, which is approved by the Health Research Council of New Zealand or the Director-General of Health, has approved the trial and was satisfied the trial was not to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled; or
- the participant did not agree, in writing, to participate in the trial, for example if the participant was unconscious.

Therefore, consenting participants are excluded from compensation in the event of an injury if it was conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled ('commercially sponsored research'), regardless of whether it has been approved by an ethics committee.

Many academic studies rely on manufacturers or distributors to supply products and/or provide funding. The line between commercially-sponsored and academic research may therefore be difficult to establish. Researchers should consider the ultimate aim of the research programme (for example, whether it is to support the approval or marketing of a product) and the degree of involvement of the manufacturer or distributor of the product.

Factors such as input into study design and documents; expectation of being able to monitor and/or audit study source documents and data (including identifiable medical records); and access to study results (especially the ability to publish independently of the researcher) should be considered when deciding whether a study is commercially sponsored.

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'). For commercially-sponsored clinical trials, researchers and sponsors must comply with the following standards.

ACC-equivalent compensation

- 17.1 Researchers must make ACC-equivalent alternative compensation available to participants for the whole period of the clinical trial.
 - 17.1.a This compensation may include treatment costs, weekly compensation for wages a participant has lost because of injury, personal help such as home help or childcare, and other types of assistance depending on the circumstances.
- 17.2 Participants' claims for alternative compensation must be resolved in a timely manner. If timely resolution is not achieved, claims should be referred to independent mediation.
- 17.3 As part of the informed consent process, researchers must clearly inform participants of:
 - whether alternative compensation arrangements are legally enforceable, and the process that will occur
 - how the researcher and their employer would support the participant in making a claim
 - 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 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.

- 17.4 Study protocols or associated documents must provide details of the availability of alternative compensation.
- 17.5 Researchers or sponsors must provide evidence to an ethics committee of appropriate levels of insurance to ensure they are able to pay out alternative compensation to participants if necessary.
 - 17.5.a In determining whether a 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 compensation.
- 17.6 Researchers must provide evidence to an ethics committee of appropriate professional indemnity.

18 Quality improvement

Introduction

Quality improvement (QI) is an umbrella term that refers to a range of activities. Quality improvement activities involve cycles of change that are linked to measurable assessment, with the goal of improving the experience, process, safety and efficiency of health care. For an activity to be considered quality improvement, it must not be conducted to generate evidence to support an intervention's efficacy, but it can involve evaluating and changing practice (Provost and Murray 2011).

In QI, generally the focus is on system functioning rather than the individual. These standards supplement guidance provided by regulatory bodies, which take precedence. Researchers, health and disability care providers and health care institutions should consider the ethical dimensions of quality improvement because:

- patients or carers can potentially experience burdens or risks through their participation in these activities
- some patients may benefit from quality improvement activities at the expense of others
- quality improvement activities involve the use of health data
- quality improvement activities can create potential conflicts of interest, when findings indicate shortfalls in care.
- if quality improvement projects are not methodologically sound, resulting knowledge cannot be shared with other health care providers, and therefore the activity is not ethically justified.

General Ethical considerations in QI

- 18.1 Service providers should inform the public that quality assurance and improvement activities are essential for the high-quality delivery of health or disability services, and that consumers' information may be used for such activities.
- 18.2 Privacy and confidentiality need to be protected except in circumstances of overriding concern, where release of information is required for reasons relating to public health or the safety of an individual.¹⁰⁰

¹⁰⁰ See Health Information Privacy Code for relevant circumstances.

- 18.2.a Any identifiable information pertaining to individuals should always be stored securely, and accessible only to the defined project team.
- 18.3 The potential gains from a quality improvement activity should justify the resources spent and the risks imposed on participants
- 18.4 A quality improvement activity should be methodologically sound (ie use improvement science and methodology).
- 18.5 A quality improvement activity should be designed to limit risks while maximising potential benefits.
- 18.6 QI activities should be transparent, and the results shared appropriately within the organisation.
- 18.7 Quality improvement results should be freely shared with others in the health care system, but participant confidentiality should be protected by putting results into non-identifiable form.
- 18.8 Each quality improvement activity should receive consideration of ethics and or supervision that is appropriate to its level of risk.
- 18.8.a Service providers should periodically review risk control measures to ascertain whether the implemented quality management activities remain effective and relevant, taking into account emerging knowledge and experience.

Table 18.1 – Identifying risk factors in quality improvement

| QI ethical risk factor |
|---|
| <p>QI activities are generally low risk. Some factors that may increase ethical risk are when:</p> <ul style="list-style-type: none"> • it poses additional risks to or burdens on a patient and/or their family or whānau beyond their routine care; for example, if a patient is required to spend additional time for data collection (e.g. Interview or focus group), provide samples not essential for care or attend extra clinic or home visits • the data to be collected is of a sensitive nature or application; for example, data that could be emotional for participants to share, or highly confidential (see chapter 13, 'health data') • secondary use of data/using data or analysis from QA or evaluation activities for another purpose • the data will be used or available in such a way that individuals may be identifiable • use of algorithms – see Chapter 13 Health Data and Emerging Technologies • it allocates interventions differently among groups of patients or staff (randomisation or the use of control groups or placebos) • comparison of cohorts |

- it is unlikely to provide direct benefits to patients¹⁰¹
 - it involves the use, storage or preservation of an individual's body parts or bodily substances.¹⁰²
-

Changes in standard of care

It is critical to consider whether a quality improvement project is going to involve a significant change in the standard or nature of clinical care and, if so, how firm the grounds are for expecting that this change will constitute an improvement, or at least not cause harm, from the participant's perspective.

Where proposed changes or other quality improvement activities are based on national and internationally recognised best practice standards (e.g. they use a recognised quality improvement methodology), ethical considerations still apply, but it is likely that implementation may proceed as part of quality improvement, as opposed to research.

When an activity tests a new, modified or previously untested intervention, service, process or programme on participants, and there is insufficient evidence to determine whether this untested aspect is safe or effective, the activity may be defined as research involving humans, and ethical Standards for research processes apply.

18.9 Where standard of care is changed based on national and international best practice, and this change is made at a system level (e.g. changing a standard practice across a district health board) to improve outcomes, specific individual consent is not required for the specific change, but routine patient consent will still be required to treat individuals.

18.9.a Prior to implementing a full system level change, best practice involves multiple Plan Do Study Act (PDSAs) small scale tests first. The end could result in a significant change, however the PDSAs are conducted to test amongst other things make sure that the change is not detrimental from the patient's perspective and staff too.

18.10 Increased ethical oversight and specific informed consent for the QI activity is required where there is a change in the standard of care for the purposes of piloting a new approach that does not have clear evidence of benefit in a similar population, or if the change is being made solely to improve efficiency or otherwise benefit the health care provider, with potential adverse effects for consumers.

¹⁰¹ These Standards have been developed on the basis of Lynn et al 2007.

¹⁰² Code of Rights right 7(10).

Informed consent and quality improvement

When a particular quality improvement activity poses risk, patients must be provided with sufficient information in an environment free of undue pressure in order to enable them to decide whether they wish to be involved – that is, to give their informed consent (Code of Health and Disability Services Consumers' Rights 1996) – just as they do in the context of clinical care or research. See '[Informed consent](#)' for more information.

18.11 Participants should be asked for their informed consent if a quality improvement activity imposes more than minimal risk, as defined by categories of risk in these Standards. See [Categories of Risk](#) for more information.

18.11.a See [Identifying risk factors in QI](#) for features that may increase risk in quality improvement.

18.12 Informed consent should be obtained where practicable prior to commencing QI activities, preferably in writing. Verbal consent and discussions related to written consent should be documented.

18.13 Information provided about quality improvement activities must be clear and understandable.

18.14 Consumers should have an opportunity to ask questions, and to reflect on their potential involvement and what it would mean for them.

18.15 QI activities should always be conducted with transparency to patients, regardless of whether consent is obtained.

Types of quality improvement activities

Quality Improvement activities should be determined using improvement science to ensure a strong evidence base. Tools for quality improvement include Shewhart Charts, driver diagrams, Quality Improvement Cycles (Plan, Do, Study, Act-PDSA), Clinical Audit, Evaluation and Programme evaluation studies, Experience Capture tools i.e. interviews and focus groups. Many of these tools are commonly used across both Research and Quality Improvement, which again illustrates the importance of ensuring good ethical practice when using these tools regardless of the context in which they are being applied.

Some recent examples of quality improvement activities are:

- the Health Quality & Safety Commission's programme looking at central line associated bacteraemia (CLAB) prevention – which resulted in the introduction of an insertion bundle (following evidence of efficacy from the United States and

an insertion pack) which resulted in a significant reduction in CLAB rates nationally

- a project aiming to improve outpatient booking and scheduling to link appointments (to decrease inconvenience for patients and wasted resources)
- a project to improve bowel cancer screening rates to increase early detection and treatment.

Clinical audit

Clinical audit is a common tool for both Quality Assurance and Quality Improvement activities. Clinical audit is defined as the systematic peer evaluation of an aspect of patient care. The process may be multidisciplinary, and involves a cycle of continuous improvement of care based on explicit and measurable indicators of quality that include a service user perspective.

Clinical audit involves investigating whether an activity meets explicit standards, as defined from national or international standards, policies, guidelines, or best practice reviews, for the purpose of checking and improving the activity audited. An audit generates knowledge for the situation in which it was undertaken, rather than generalisable knowledge. It should provide feedback primarily to the local setting or particular service involved, although it may also involve a wider dissemination by way of publication or presentation of its findings.

Healthcare providers should restrict access to personal health information to those who the healthcare provider employs or contracts, the funder of the service and agencies responsible for overseeing the safety and quality of the service. Such information should be used solely for the purpose of auditing a service.

In addition, clinical audit is often used interchangeably with other non-research activities such as service evaluation and outcome analysis. Briefly, clinical audit measures practice against a standard, service evaluation measures current practice of 'how much, how many and how well' of the service, while outcome analysis looks at outcomes of practice focussing often on management and complication rates. Specifically, outcome analyses are conducted on activities already being undertaken and does not provide new knowledge for an intervention where no knowledge exists in that area¹⁰³.

¹⁰³ For more information please see Towards Clinical Excellence – Ministry of Health (2002).

Some examples of audits and related activities are:

- resource utilisation reviews, which evaluate the use of resources in a particular health or disability service activity (e.g. chest X-rays for patients with a particular diagnosis against evidence-based Choosing Wisely recommendations.)
- reviewing clinical records against documentation standards
- reviewing the completeness of medication charts against the national standards for the National Medication Charting
- assessment and medical management of hospitalised elderly patients admitted to acute medicine services with Delirium
- the completeness of blood administration forms for patients who have received blood products
- use of outcome-based measures for ECT
- use of Analgesia for Thoracotomies
- secondary prevention post-CABG

Privacy and confidentiality risk factors

Audits may present more than minimal risk if:

- the audit data will be used, stored, transported or made available (including in written outputs) in such a way that may identify individuals
- access to personal information will extend beyond those who are members of the clinical care team, or to others who normally do not have access to patients' records, or to other relevant data sets
- the audit activity involves individuals, people or communities who are rare, small or unique and therefore could be easily identified (e.g. people with a rare condition).

Benefits and professional practice

18.16 Health service providers should ensure that the audit and audit-related activities they undertake have the potential to improve health outcomes.

18.17 People conducting audits or related activities must operate under professional standards or employment requirements that oblige them to maintain the confidentiality of patient data.

18.18 Audits should be conducted by people under a professional or an employment obligation, or student candidates, to maintain patient confidentiality. Such activity may be initiated from outside the organisation or by the organisation itself, and may be conducted by the organisation (an internal audit or related activity) or by a contracted party external to it (an external audit or related activity). *Services should restrict access to confidential medical and personal information to those individuals the service provider employs or contracts, the funder of the service and*

agencies responsible for overseeing the safety and quality of the service. Such information should be used solely for the purpose of auditing a service.

Use of health data for audits and related activities

- 18.19 It may be ethical to use health information without additional or specific consent for the purpose of audits and related activities, as these activities are sometimes an essential part of high-quality health care delivery and may be one of the reasons why the data were collected.
- 18.20 In the case of audits and related activities, the use of record linkages within organisations without specific or additional consent is ethically justifiable when these activities are part of high-quality health care delivery¹⁰⁴.
- 18.21 When the activity involves disclosure, it must be part of a professionally recognised external quality assurance programme in order to permit the disclosure of the person's health information¹⁰⁵.
- 18.22 Health service providers should ensure that they comply with internal organisational requirements in respect of all audits and related activities that they conduct in or through the organisation.
- 18.22.a The appropriate approach will vary from organisation to organisation; as such, organisations might also specify their own processes regarding notification or approval of audits and related quality activities.

Audits that use human tissue

- 18.23 An audit requires ethical review if it involves the use, collection or storage of human tissue without consent, other than in accordance with a statutory exception (set out at section 20(f) of the [Human Tissue Act 2008](#) and Right 7(10)(c) of the [Code of Health and Disability Services Consumers' Rights 1996](#)).

Evaluation and programme evaluation

Evaluation studies aim to determine the relevance, effectiveness and impact of activities in the light of their objectives. They may evaluate the structure, process or outcome of an activity.

Programme evaluation focuses on a whole programme, rather than specific interventions, where the sole purpose of the exercise is to refine and improve the

¹⁰⁴ Quality audits, including those activities that involve linking data, must fall under a directly related purpose of the information collected. See <https://www.privacy.org.nz/assets/Files/Codes-of-Practice-materials/HIPC-1994-2008-revised-edition.pdf> for more information.

¹⁰⁵ See Rule 11 of the Health Information Privacy Code.

programme or monitoring. At a minimum, the description of a programme evaluation should convey the idea that evaluation assesses the value of a programme as a whole in order to refine, improve or possibly cease it.

If a programme was not originally designed based on robust evidence,¹⁰⁶ there are often significant uncertainties as to the benefits and harms posed by its active components (specific interventions).

18.24 In this case, programmes and subsequent programme evaluations may be considered as research.

Accountability for the ethical conduct of quality improvement

Health care organisations that conduct quality assurance and improvement activities are accountable for the ethical conduct of those activities and must ensure there is appropriate ethical oversight for activities in relation to their risk (Lynn et al 2007). Organisations should consider the following, alongside the obligations of individual practitioners:

18.25 Practices that ensure accountability for the ethical conduct of quality improvement should be integrated into practices that ensure accountability for clinical care.

18.26 Regulatory institutions¹⁰⁷ should inform members about their professional responsibility to improve quality, identify the basic quality improvement skills members should have, educate members about standards for ethical conduct of quality improvement and incorporate quality improvement into professional codes of ethics.

18.27 Health service providers should inform members about their responsibility to improve quality, the need to ensure that their employees have basic quality improvement skills and the standards for ethical conduct of quality improvement.

18.28 Leaders in professional education should press for greater emphasis on the responsibility of health professionals to improve the quality of care and the development of quality improvement skills in educational curricula, including management of the ethical dimensions of quality improvement.

¹⁰⁶ For example, evidence that is generated from studies that have a priori criteria, an objective process, transparent, reproducible, using validated methods to distinguish high vs. low quality evidence and draws conclusions based on the body of evidence and its limitations.

¹⁰⁷ See <https://www.mcnz.org.nz/support/related-agencies/health-professional-regulatory-bodies/> for examples

- 18.29 Service providers should tell people seeking health care why quality improvement activities are important to the quality of their care, and how to obtain more information about quality improvement programmes if they want it.
- 18.30 Health care organisations should develop patient education materials about patient rights and responsibilities with respect to quality improvement and the conduct of quality improvement within the organisation.
- 18.31 Arrangements for deciding which quality improvement projects qualify as human research, and should therefore have increased ethical oversight, should be tested in practical application, aiming to implement clear definitions and accepted procedures.

19 *References*

20 *Bibliography*

Appendix one – other ethical guidance documents

Appendix two – glossary

PART THREE

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19 References

- ACART. 2005. *Guidelines for Research on Gametes and Non-viable Embryos*. Wellington: Advisory Committee on Assisted Reproductive Technology. URL: https://acart.health.govt.nz/system/files/documents/publications/guidelines_for_research_on_gametes_and_nonviable_embryos.pdf (accessed 18 June 2019).
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. 2014. *TCPS2: 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 18 June 2019).
- CEBM. 2019. Levels of Evidence. URL: www.cebm.net/category/ebm-resources/loe/ (accessed 13 June 2019). CIOMS, WHO. 2016. *International Ethical Guidelines for Health-related Research involving Humans*. Geneva: Council for International Organizations of Medical Sciences. URL: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> (accessed 18 June 2019).
- Committee on Quality of Health Care in America. 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press.
- Dal-Re R, Solá CA, Gil-Aguado A, et al. 2008. When should re-consent of subjects participating in a clinical trial be requested? A case-oriented algorithm to assist in the decision-making process. *Clinical Pharmacology & Therapeutics* 83(5): 788–93.
- Data Governance Institute. 2017. The basic information. URL: www.datagovernance.com/the-basic-information (accessed 17 June 2019).
- Data Linkage Western Australia. 2019. What is data linkage? URL: www.datalinkage-wa.org.au/frequently-asked-questions/ (accessed 14 June 2019).
- Department of Economic and Social Affairs. 2006. *United Nations Convention on the Rights of Persons with Disabilities*. URL: <https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities.html> (accessed 10 October 2019).
- Dickson-Swift V, James E L, Kippen S, & Liamputtong P. 2007. Doing sensitive research: what challenges do qualitative researchers face? *Qualitative research* 7(3): 327-353.

- Fenech M, Strukelj N, Buston O. 2018. *Ethical, Social, and Political Challenges of Artificial Intelligence in Health*. London: Wellcome Trust. URL: <https://wellcome.ac.uk/funding/ethical-social-and-political-challenges-using-artificial-intelligence-healthcare> (accessed 17 June 2019).
- Gilbert T, Bosquet A, Thomas-Antérion C, et al. 2017. Assessing capacity to consent for research in cognitively impaired older patients. *Clinical Interventions in Aging* 12: 1553–63.
- Health and Disability Ethics Committees. 2018. HDEC review and approvals. URL: <https://ethics.health.govt.nz/hdec-review-and-approvals> (accessed 5 June 2019).
- 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 10 October 2019)
- Health Research Council. 2018. *HRC Research Ethics Guidelines*.
- Hirschhorn LR, Ramaswamy R, Devnani M, et al. 2018. Research versus practice in quality improvement? Understanding how we can bridge the gap. *International Journal for Quality in Health Care* 30: 24–8. URL: https://academic.oup.com/intqhc/article/30/suppl_1/24/4852804 (accessed 5 June 2019).
- Health Quality and Safety Commission. 2017. *National Adverse Events Reporting Policy*. Health Quality and Safety Commission.
- 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> (accessed 18 June 2019).
- HRC. 2014b. *Pacific Health Research Guidelines*. Wellington: Health Research Council of New Zealand. URL: www.hrc.govt.nz/sites/default/files/Pacific%20Health%20Research%20Guidelines%202014.pdf (accessed 6 June 2019).
- HRC. (nd). Seeking Ethical Review. URL: www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval (accessed 5 June 2019).
- Hudson, M., Anderson, T., Dewes, T. K., Temara, P., Whaanga, H., & Roa, T. (2017). "He Matapihi ki te Mana Raraunga" - Conceptualising Big Data through a Māori lens. In H. Whaanga, T. T. A. G. Keegan, & M. Apperley (Eds.), *He Whare Hangarau Māori - Language, culture & technology* (pp. 64–73). Hamilton, New Zealand: Te Pua Wānanga ki te Ao / Faculty of Māori and Indigenous Studies, the University of Waikato.

- International Committee of Medical Journal Editors. 2004. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and editing for biomedical publication*. International Committee of Medical Journal Editors.
- Iphofen R. 2009. *Ethical Decision Making in Social Research: a practical guide*. Hampshire: Palgrave Macmillan.
- 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 18 June 2019).
- 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 18 June 2019).
- Hudson M, Milne M, Reynolds P, et al. 2010. *Te Ara Tika: Guidelines for Māori research ethics*. Wellington: Health Research Council of New Zealand. URL: <http://www.hrc.govt.nz/sites/default/files/Te%20Ara%20Tika%20FINAL%202010.pdf> (accessed 10 October 2019).
- 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 18 June 2019).
- 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 18 June 2019).
- Jake Earl. 2019. Innovative Practice, Clinical Research, and the Ethical Advancement of Medicine. *The American Journal of Bioethics* 19(6): 7-18
DOI:10.1080/15265161.2019.1602175
- Jiang F, Jiang Y, Zhi H, et al. 2017. Artificial intelligence in healthcare: past, present and future. *Stroke and Vascular Neurology* 2(4): 230–43.
- Jones B, Vaux E, Olsson-Brown A. 2019. How to get started in quality improvement. *BMJ* 364: k5408. URL: <https://www.bmj.com/content/364/bmj.k5437> (accessed 5 June 2019).
- Lange MM, Rogers W, Dodds S. 2013. Vulnerability in research ethics: a way forward. *Bioethics* 27(6): 333–40.

- Lynn J, Baily MA, Bottrell M, et al. 2007. The ethics of using quality improvement methods in health care. *Annals of Internal Medicine* 146(9): 666–73.
- New Zealand Medicines and Medical Devices Safety Authority. 2015. *Pharmacovigilance*. URL: <https://medsafe.govt.nz/regulatory/pharmacovigilance.asp>
- Millum J, Grady C. 2013. The ethics of placebo-controlled trials: methodological justifications. *Contemporary Clinical Trials* 36(2).
- Ministry of Business, Innovation and Employment and Ministry of Health. 2017. *New Zealand Health Research Strategy 2017–2027*. Wellington: Ministry of Business, Innovation and Employment and Ministry of Health.
- Ministry of Health. 1998. *Consent in Child and Youth Health: Information for Practitioners*. Wellington: Ministry of Health.
- 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 18 June 2019).
- 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 18 June 2019).
- Ministry of Health. 2008. *Standard Operating Procedures for Health and Disability Ethics Committees*. Wellington: Ministry of Health. URL: <https://ethics.health.govt.nz/operating-procedures> (accessed 18 June 2019).
- Ministry of Health. 2014a. *'Ala Mo'ui: Pathways to Pacific Health and Wellbeing 2014–2018*. Wellington: Ministry of Health. URL: www.health.govt.nz/publication/ala-moui-pathways-pacific-health-and-wellbeing-2014-2018 (accessed 5 June 2019).
- Ministry of Health. 2014b. He Korowai Oranga. URL: www.health.govt.nz/our-work/populations/maori-health/he-korowai-oranga (accessed 5 June 2019).
- Ministry of Health. 2017a. *HISO 10001:2017 Ethnicity Data Protocols*. Wellington: Ministry of Health. URL: <https://www.health.govt.nz/publication/hiso-100012017-ethnicity-data-protocols> (accessed 19 June 2019).
- Ministry of Social Development. 2001. *New Zealand Disability Strategy*. Wellington: Ministry of Social Development.

- Ministry of Social Development. 2016. *New Zealand Disability Strategy 2016–2026*. Wellington: Ministry of Social Development.
- National Disability Authority. 2009. *Ethical Guidance for Research with People with Disabilities*. Dublin: National Disability Authority.
- NHMRC. 2018. *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*. Canberra: National Health and Medical Research Council.
- NIMH. (nd). NIMH Guidance on Risk-Based Monitoring. URL: www.nimh.nih.gov/funding/clinical-research/nimh-guidance-on-risk-based-monitoring.shtml (accessed 12 June 2019).
- Nuffield Council on Bioethics. 2018. *Artificial intelligence (AI) in healthcare and research*. Briefing note. London: Nuffield Council on Bioethics. URL: <http://nuffieldbioethics.org/project/briefing-notes/artificial-intelligence-ai-healthcare-research> (accessed 17 June 2019).
- Parliamentary Counsel Office. 2000. *New Zealand Public Health and Disability Act*. URL: <http://legislation.govt.nz/act/public/2000/0091/72.0/DLM80051.html> (accessed 10 October 2019).
- Parliamentary Counsel Office. 2004. *Care of Children Act 2004*. URL: <http://www.legislation.govt.nz/act/public/2004/0090/67.0/DLM317233.html> (accessed 10 October 2019).
- Parliamentary Counsel Office. 2008. *Human Tissue Act*. URL: <http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html>.
- Provost L, Murray S. 2011. *The Health Care Data Guide: Learning from Data for Improvement*. San Francisco: Jossey-Bass.
- Falevitu: A literature review on culture and family violence in seven Pacific communities in New Zealand, Peteru 2012
- Pulotu-Endemann FE. 2001. *Fonofale Model of Health*. Auckland: Hauora. URL: www.hauora.co.nz/resources/Fonofalemodelexplanation.pdf (accessed 1 February 2018).
- Rennie S, Suzanne D, Allison M, Adam G, Winfred K L, Joseph D T, and Gail E H. 2019. The Role of Inclusion Benefits in Ethics Committee Assessment of Research Studies. *Ethics & human research* 41(3): 13-22.
- Retief M, Letšosa R. 2018. Models of disability: A brief overview. *HTS Teologiese Studies/Theological Studies* 74(1). DOI: <https://doi.org/10.4102/hts.v74i1.4738>.

- Rogers W, Lange MM. 2013. Rethinking the vulnerability of minority populations in research. *American Journal of Public Health* 103(12): 2141–6.
- Scottish Government. 2012. *Joined-up Data for Better Decisions: Guiding principles for data linkage*. Edinburgh: Scottish Government. URL: <http://www.datalinkagescotland.co.uk/safeguarding> (accessed 19 June 2019).
- Stats NZ, Privacy Commissioner. 2018. Principles for safe and effective use of data and analytics. URL: www.privacy.org.nz/news-and-publications/guidance-resources/principles-for-the-safe-and-effective-use-of-data-and-analytics-guidance/ (accessed 17 June 2019).
- Sullivan MJ. 2009. Philosophy, Ethics, and the Disability Community. In: DM Mertens, PE Ginsberg (eds), *The Handbook of Social Research Ethics*. Thousand Oaks: Sage Publications.
- Sweeney L, Yoo J S, Perovich L, Boronow K E, Brown P, and Brody JG. 2017. Reidentification Risks in HIPAA Safe Harbor Data: A study of data from one environmental health study. *Technology Science*. URL: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6344041/> (accessed 25 September 2019).
- 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 (accessed 19 June 2019).
- The Health Foundation. August 2013. *Quality improvement made simple: What everyone should know about health care quality improvement. 2nd edition*. London: The Health Foundation. URL: <https://www.health.org.uk/sites/default/files/QualityImprovementMadeSimple.pdf> (accessed 24 September 2019).
- United Nations Convention on the Rights of Persons with Disabilities*. 2006. Articles 3, 4 & 12. URL: <https://www.un.org/disabilities/documents/convention/convoptprot-e.pdf>
- United Nations Framework Convention on Climate Change Secretariat. 2018. 2018 Talanoa Dialogue Platform. URL: <https://unfccc.int/process/the-paris-agreement/2018-talanoa-dialogue-platform> (accessed 6 June 2019).
- Van Der Graaf R, Van der Zande I S, Van Delden J J. 2019. How the CIOMS guidelines contribute to fair inclusion of pregnant women in research. *Bioethics* 33(3): 377-383. Doi: 10.1111/bioe.12520

Weijer C, Grimshaw J M, Eccles M P, McRae A D, White A, Brehaut J C, Taljaard M. 2012. The Ottawa statement on the ethical design and conduct of cluster randomised trials. *PLoS medicine* 9(11): e1001346.

Wahaanga H, Keegan Te T, Apperley M (eds). 2017. *He Whare Hangarau Māori: Language, culture & technology*. Hamilton: Te Pua Wānanga ki te Ao/Faculty of Māori and Indigenous Studies, Te Whare Wānanga o Waikato/University of Waikato.

WHO. 2014. Mental health: a state of well-being. (accessed 5 June 2019).

WHO. 2019a. Health equity. URL: http://origin.who.int/topics/health_equity/en/ (accessed 5 June 2019).

WHO. 2019b. Health Impact Assessment. URL: www.who.int/hia/about/glos/en/index1.html (accessed 5 June 2019).

Williamson B. 2015. Access. In Adams R, Reiss B, Serlin D (eds). 2015. *Keywords for Disability Studies*. New York: New York University Press.

World Intellectual Property Organization. 2013. *Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled*. URL: <https://wipolex.wipo.int/en/text/301016>

WMA. 2006. *Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks*. Washington: World Medical Association. URL: www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/ (accessed 19 June 2019).

WMA. 2017. *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 19 June 2019).

20 Bibliography

- ACART. 2005. *Guidelines for Research on Gametes and Non-viable Embryos*. Wellington: Advisory Committee on Assisted Reproductive Technology. URL: https://acart.health.govt.nz/system/files/documents/publications/guidelines_for_research_on_gametes_and_nonviable_embryos.pdf (accessed 18 June 2019).
- 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/pacsrch--guide.pdf (accessed 18 June 2019).
- Beaton A, Smith B, Toki K, et al. 2015. Engaging Māori in biobanking and genetic research: Legal, ethical, and policy challenges. *The International Indigenous Policy Journal* 6(3).
- Berg RM, Møller 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 18 June 2019).
- 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 18 June 2019).
- 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 18 June 2019).
- Calveley 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 18 June 2019).
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. 2014. *TCPS2: 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 18 June 2019).
- Careerforce. 2015. *Pacific Values and Principles*. Christchurch: Careerforce. URL: <https://library.careerforce.org.nz/Learning%20Assessment%20Resources/LG25987-3.0.pdf> (accessed 18 June 2019).
- Cassell J, Young A, 2002. Why we should not seek individual informed consent for

- participation in health services research. *Journal of Medical Ethics* 28: 313-317.
- CEBM. 2019. Levels of Evidence. URL: www.cebm.net/category/ebm-resources/loe/ (accessed 13 June 2019).
- CIOMS, WHO. 2016. *International Ethical Guidelines for Health-related Research involving Humans*. Geneva: Council for International Organizations of Medical Sciences. URL: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> (accessed 18 June 2019).
- Clinical Audit and Effectiveness Department. 2007. *The Difference between Audit & Research*. London: NHS Blood and Transplant.
- COPE. 2017 *Ethical Guidelines for Peer Reviewers*. Committee on Publication Ethics. URL: http://publicationethics.org/files/Ethical_Guidelines_For_Peer_Reviewers_2.pdf (accessed 18 June 2019).
- Committee on Quality of Health Care in America. 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press.
- Counties Manukau District Health Board. 2016. *Guideline: Ethical Guideline for Quality Improvement*. Auckland: Counties Manukau District Health Board. URL: <http://koawatea.co.nz/wp-content/uploads/2017/08/Ethical-Guidelines-for-Quality-Improvement-Gulideline.pdf> (accessed 18 June 2019).
- Cunningham C. 2000. A framework for addressing Māori knowledge in research, science and technology. *Pacific Health Dialog* 7: 62–9.
- Dal-Re R, Solá CA, Gil-Aguado A, et al. 2008. When should re-consent of subjects participating in a clinical trial be requested? A case-oriented algorithm to assist in the decision-making process. *Clinical Pharmacology & Therapeutics* 83(5): 788–93.
- Data Governance Institute. 2017. The basic information. URL: www.datagovernance.com/the-basic-information (accessed 17 June 2019).
- Data Linkage Western Australia. 2019. What is data linkage? URL: <https://www.datalinkage-wa.org.au/frequently-asked-questions/> (accessed 14 June 2019).
- 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 18 June 2019).

- Douglass A. 2016. *Mental Capacity: Updating New Zealand's law and practice*. Dunedin: New Zealand Law Foundation.
- Fenech M, Strukelj N, Buston O. 2018. *Ethical, Social, and Political Challenges of Artificial Intelligence in Health*. London: Wellcome Trust. URL: <https://wellcome.ac.uk/funding/ethical-social-and-political-challenges-using-artificial-intelligence-healthcare> (accessed 17 June 2019).
- Gilbert T, Bosquet A, Thomas-Antérion C, et al. 2017. Assessing capacity to consent for research in cognitively impaired older patients. *Clinical Interventions in Aging* 12: 1553–63.
- Gillett G. 2014. Bioethical issues. *Journal of Law and Medicine* 21: 780–8.
- Gopichandran V, Luyckx VA, et al. 2016. Developing the ethics of implementation research in health. *Implementation Science*. URL: <https://implementationscience.biomedcentral.com/articles/10.1186/s13012-016-0527-y> (accessed 07 November 2019).
- Health and Disability Ethics Committees. 2018. HDEC review and approvals. URL: <https://ethics.health.govt.nz/hdec-review-and-approvals> (accessed 5 June 2019).
- Hirschhorn LR, Ramaswamy R, Devnani M, et al. 2018. Research versus practice in quality improvement? Understanding how we can bridge the gap. *International Journal for Quality in Health Care* 30: 24–8. URL: https://academic.oup.com/intqhc/article/30/suppl_1/24/4852804 (accessed 5 June 2019).
- 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 18 June 2019).
- 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> (accessed 18 June 2019).
- HRC. 2014a. *Guidance Notes on Research Ethics*. Wellington: Health Research Council of New Zealand. URL: http://www.hrc.govt.nz/sites/default/files/HRC%20Guidance%20Notes%20on%20Research%20Ethics%20-%20November%202014_0.pdf (accessed 18 June 2019).

- HRC. 2014b. *Pacific Health Research Guidelines*. Wellington: Health Research Council of New Zealand. URL: www.hrc.govt.nz/sites/default/files/Pacific%20Health%20Research%20Guidelines%202014.pdf (accessed 6 June 2019).
- HRC. (nd). Seeking Ethical Review. URL: www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval (accessed 5 June 2019).
- 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*. Hamilton: Te Pua Wānanga ki te Ao/Faculty of Māori and Indigenous Studies, Te Whare Wānanga o Waikato/University of Waikato.
- International Committee of Medical Journal Editors. 2004. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and editing for biomedical publication*. International Committee of Medical Journal Editors.
- Iphofen R. 2009. *Ethical Decision Making in Social Research: a practical guide*. New York: Palgrave Macmillan.
- 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 18 June 2019).
- 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 18 June 2019).
- Hudson M, Milne M, Reynolds P, et al. 2010. *Te Ara Tika: Guidelines for Māori research ethics*. Wellington: Health Research Council of New Zealand.
- 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 18 June 2019).
- 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 18 June 2019).

- Jiang F, Jiang Y, Zhi H, et al. 2017. Artificial intelligence in healthcare: past, present and future. *Stroke and Vascular Neurology* 2(4): 230–43.
- Jones B, Vaux E, Olsson-Brown A. 2019. How to get started in quality improvement. *BMJ* 364: k5408. URL: <https://www.bmj.com/content/364/bmj.k5437> (accessed 5 June 2019).
- 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 18 June 2019).
- Lange MM, Rogers W, Dodds S. 2013. Vulnerability in research ethics: a way forward. *Bioethics* 27(6): 333–40.
- 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 18 June 2019).
- Lynn J, Baily MA, Bottrell M, et al. 2007. The ethics of using quality improvement methods in health care. *Annals of Internal Medicine* 146(9): 666–73.
- Manning J. 2009. *The Cartwright Papers: Essays on the cervical cancer inquiry 1987–88*. Wellington: Bridget Williams Books.
- Manning J. 2016a. Non-consensual clinical research in New Zealand: law reform urgently needed. *Journal of Law and Medicine* 23(3): 516–30. URL: <https://www.ncbi.nlm.nih.gov/pubmed/27323631> (accessed 18 June 2019).
- Manning J. 2016b. '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*. Wellington: Thomson Reuters.
- Medical Council of New Zealand. (nd). Current standards. URL: www.mcnz.org.nz/our-standards/current-standards (accessed 18 June 2019).
- Memorial Health. (nd). *Determining the difference between clinical research and quality/performance improvement at Memorial University Medical Center*. Savannah: Memorial Health.
- 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 18 June 2019).

- Millum J, Grady C. 2013. The ethics of placebo-controlled trials: methodological justifications. *Contemporary Clinical Trials* 36(2).
- 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 18 June 2019).
- Ministry of Business, Innovation and Employment and Ministry of Health. 2017. *New Zealand Health Research Strategy 2017–2027*. Wellington: Ministry of Business, Innovation and Employment and Ministry of Health.
- Ministry of Health. 1998. *Consent in Child and Youth Health: Information for Practitioners*. Wellington: Ministry of Health.
- 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/$FILE/OperationalStandard_final.pdf) (accessed 18 June 2019).
- Ministry of Health. 2006. *Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research*. Wellington: Ministry of Health. URL: [www.moh.govt.nz/notebook/nbbooks.nsf/0/7D723EE803F89C67CC2576D5006CBBCC/\\$file/guidelines-stem-cell-use.pdf](http://www.moh.govt.nz/notebook/nbbooks.nsf/0/7D723EE803F89C67CC2576D5006CBBCC/$file/guidelines-stem-cell-use.pdf) (accessed 18 June 2019).
- 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 18 June 2019).
- Ministry of Health. 2008. *Standard Operating Procedures for Health and Disability Ethics Committees*. Wellington: Ministry of Health. URL: <https://ethics.health.govt.nz/operating-procedures> (accessed 18 June 2019).
- Ministry of Health. 2014a. *'Ala Mo'ui: Pathways to Pacific Health and Wellbeing 2014–2018*. Wellington: Ministry of Health. URL: www.health.govt.nz/publication/ala-moui-pathways-pacific-health-and-wellbeing-2014-2018 (accessed 5 June 2019).
- Ministry of Health. 2014b. He Korowai Oranga. URL: www.health.govt.nz/our-work/populations/maori-health/he-korowai-oranga (accessed 5 June 2019).
- Ministry of Health. 2016. *New Zealand Health Strategy: Future direction*. Wellington: Ministry of Health. URL: <https://www.health.govt.nz/system/files/documents/publications/new-zealand-health-strategy-futuredirection-2016-apr16.pdf> (accessed 18 June 2019).

- Ministry of Health. 2017a. *HISO 10001:2017 Ethnicity Data Protocols*. Wellington: Ministry of Health. URL: <https://www.health.govt.nz/publication/hiso-100012017-ethnicity-data-protocols> (accessed 19 June 2019).
- Ministry of Health. 2017b. Therapeutic products regulatory regime. URL: www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime (accessed 19 June 2019).
- 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/$file/Pacific_analysis_framework.pdf) (accessed 19 June 2019).
- Ministry of Social Development. 2001. *New Zealand Disability Strategy*. Wellington: Ministry of Social Development.
- Ministry of Social Development. 2016. *New Zealand Disability Strategy 2016–2026*. Wellington: Ministry of Social Development.
- National Disability Authority. 2009. *Ethical Guidance for Research with People with Disabilities*. Dublin: National Disability Authority.
- National Ethics Advisory Committee. 2003. *Ethical Review of Observational Research, Audit and Related Activities: Discussion document*. Wellington: National Health and Medical Research Council. URL: [www.moh.govt.nz/notebook/nbbooks.nsf/0/38bd184e5f5983a2cc256e14007a10c4/\\$FILE/EthicalReviewObservationalResearch.pdf](http://www.moh.govt.nz/notebook/nbbooks.nsf/0/38bd184e5f5983a2cc256e14007a10c4/$FILE/EthicalReviewObservationalResearch.pdf) (accessed 19 June 2019).
- 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 19 June 2019).
- National Ethics Advisory Committee – Kāhui Matatika o te Motu. 2012. *Āhuratanga ū ki te Tika me te Pono mō te Rangahau Māori: Māori research ethics: An overview*. Wellington: Ministry of Health. URL: <https://neac.health.govt.nz/system/files/documents/publications/neac-maori-research-ethics-an-overview-2012.pdf> (accessed 19 June 2019).
- NHMRC. 2018. *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*. Canberra: National Health and Medical Research Council.
- NIMH. (nd). NIMH Guidance on Risk-Based Monitoring. URL: www.nimh.nih.gov/funding/clinical-research/nimh-guidance-on-risk-based-monitoring.shtml (accessed 12 June 2019).

- 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 19 June 2019).
- Nuffield Council on Bioethics. 2018. *Artificial intelligence (AI) in healthcare and research*. Briefing note. London: Nuffield Council on Bioethics. URL: <http://nuffieldbioethics.org/project/briefing-notes/artificial-intelligence-ai-healthcare-research> (accessed 17 June 2019).
- 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 19 June 2019).
- Pratt B, Paul A, et al. 2017. Ethics of health policy and systems research: a scoping review of the literature. *Health Policy and Planning* 32(6): 890-910. URL: <https://academic.oup.com/heapol/article/32/6/890/3072655> (accessed 15 November 2019).
- Provost L, Murray S. 2011. *The Health Care Data Guide: Learning from Data for Improvement*. San Francisco: Jossey-Bass.
- 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 & Risk* 9(3–4): 151–77. URL: <https://doi.org/10.1093/lpr/mgq006> (accessed 19 June 2019).
- Rogers W, Lange MM. 2013. Rethinking the vulnerability of minority populations in research. *American Journal of Public Health* 103(12): 2141–6.
- 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 19 June 2019).
- Scottish Government. 2012. *Joined-up Data for Better Decisions: Guiding principles for data linkage*. Edinburgh: Scottish Government. URL: <http://www.datalinkagescotland.co.uk/safeguarding> (accessed 19 June 2019).

- 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.
- Stats NZ, Privacy Commissioner. 2018. Principles for safe and effective use of data and analytics. URL: www.privacy.org.nz/news-and-publications/guidance-resources/principles-for-the-safe-and-effective-use-of-data-and-analytics-guidance/ (accessed 17 June 2019).
- Sullivan MJ. 2009. Philosophy, Ethics, and the Disability Community. In: DM Mertens, PE Ginsberg (eds), *The Handbook of Social Research Ethics*. Thousand Oaks: Sage Publications.
- 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 (accessed 19 June 2019).
- United Nations Framework Convention on Climate Change Secretariat. 2018. 2018 Talanoa Dialogue Platform. URL: <https://unfccc.int/process/the-paris-agreement/2018-talanoa-dialogue-platform> (accessed 6 June 2019).
- University of Otago. 2011. *Pacific Research Protocols*. Dunedin: University of Otago. URL: www.otago.ac.nz/research/otago085503.pdf (accessed 19 June 2019).
- US Department of Health and Human Services Health Resources and Service Administration. 2011. *Quality Improvement*. Rockville, MD: US Department of Health and Human Services Health Resources and Service Administration. URL: www.hrsa.gov/sites/default/files/quality/toolbox/508pdfs/qualityimprovement.pdf (accessed 19 June 2019).
- 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-e10. DOI: 10.1097/CCM.0000000000002023 (accessed 19 June 2019).
- Wahaanga H, Keegan Te T, Apperley M (eds). 2017. *He Whare Hangarau Māori: Language, culture & technology*. Hamilton: Te Pua Wānanga ki te Ao/Faculty of Māori and Indigenous Studies, Te Whare Wānanga o Waikato/University of Waikato.
- WHO. 2014. Mental health: a state of well-being. URL: **Error! Hyperlink reference not valid.** (accessed 5 June 2019).
- WHO. 2019a. Health equity. URL: http://origin.who.int/topics/health_equity/en/ (accessed 5 June 2019).

- WHO. 2019b. Health Impact Assessment. URL: www.who.int/hia/about/glos/en/index1.html (accessed 5 June 2019).
- Williamson B. 2015. Access. In Adams R, Reiss B, Serlin D (eds). 2015. *Keywords for Disability Studies*. New York: New York University Press.
- WMA. 2006. *Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks*. Washington: World Medical Association. URL: www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/ (accessed 19 June 2019).
- WMA. 2017. *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 19 June 2019).
- 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.
- Zwitter A. 2014. Big data ethics. *Big Data & Society* 1(2). URL: <http://journals.sagepub.com/doi/abs/10.1177/2053951714559253#articleCitationDownloadContainer> (accessed 18 June 2019).

Appendix one – other ethical guidance documents

The following documents provide further general ethical guidance for the New Zealand context.

Guidelines published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

HRC. (nd). *Health Research and Privacy: Guidance notes for health researchers and ethics committees*. Wellington: Health Research Council. URL: www.hrc.govt.nz/sites/default/files/Research%20involving%20personal%20health%20information.pdf (accessed 19 June 2019).

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 18 June 2019).

HRC. 2010. *Guidelines for Researchers on Health Research Involving Māori* – Health Research Council. 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> (accessed 18 June 2019).

HRC. 2014b. *Pacific Health Research Guidelines*. Wellington: Health Research Council of New Zealand. URL: www.hrc.govt.nz/sites/default/files/Pacific%20Health%20Research%20Guidelines%202014.pdf (accessed 6 June 2019).

HRC. 2017. *Research Ethics Guidelines*. Wellington: Health Research Council. URL: <http://www.hrc.govt.nz/sites/default/files/HRC%20Research%20Ethics%20Guidelines%20-%20December%202017.pdf> (accessed 19 June 2019): especially section 3.6, 'Collection and use of human materials'.

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 18 June 2019).

- 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 18 June 2019).
- Hudson M, Milne M, Reynolds P, et al. 2010. *Te Ara Tika: Guidelines for Māori research ethics*. Wellington: Health Research Council of New Zealand.
- Medsafe, Ministry of Health. *Guideline on the Regulation of Therapeutic Products in New Zealand). Part 11: Clinical trials – regulatory approval and good clinical practice requirements*. Wellington: Medsafe, Ministry of Health. URL: <https://medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part11.pdf> (accessed 19 June 2019).
- Ministry of Business, Innovation and Employment and Ministry of Health. 2017. *New Zealand Health Research Strategy 2017–2027*. Wellington: Ministry of Business, Innovation and Employment and Ministry of Health.
- 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/0/7D723EE803F89C67CC2576D5006CBBC/\\$file/guidelines-stem-cell-use.pdf](http://www.moh.govt.nz/notebook/nbbooks.nsf/0/7D723EE803F89C67CC2576D5006CBBC/$file/guidelines-stem-cell-use.pdf) (accessed 18 June 2019).
- Ministry of Health. 2007. *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes*. Wellington: Ministry of Health. URL: www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0 (accessed 19 June 2019).
- Ministry of Health. 2008. *Standard Operating Procedures for Health and Disability Ethics Committees*. Wellington: Ministry of Health. URL: <https://ethics.health.govt.nz/operating-procedures> (accessed 18 June 2019).
- Standards New Zealand. 2010. *Non-Therapeutic Use of Human Tissue NZS 8135:2009*. Wellington: Standards New Zealand.

Appendix two – glossary

| Term | Definition |
|---|---|
| ACC | Accident Compensation Corporation |
| Bioavailability study | A study examining the rate and extent at which a drug, when administered in a pharmaceutical dosage form, becomes available, either at the site of pharmacological effect or systemically within the body. |
| Bioequivalence study | A study aiming to show that the bioavailability of one formulation of a drug is equivalent to another formulation of the same drug. |
| Clinical trial/ interventional trial | Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes and preventive care. This definition includes phase I–phase IV trials. |
| Commercially sponsored | Describes research conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. |
| Conflict of interest | A situation in which 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 | An individual or group responsible for protecting, monitoring the use of or managing Māori research data or samples; the term is not limited to a research projects (e.g., a custodian may be responsible for a databank or biobank) |
| Data and safety monitoring committee (DSMC) | A body that advises the study team and study sponsor, and is responsible for monitoring emerging data during the course of a study. The purpose of these roles is to ensure both that the participants are safe and that the study is conducted to a high quality, so that it generates reliable answers to its study questions. The DSMC may be independent, or may be constituted from those conducting the study. Another term for a DSMC is ‘data and safety monitoring board’. |

| Term | Definition |
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| End-point/outcome measure | A pre-specified outcome variable of interest to a study. The primary end-point is the most important outcome, and should reflect clinically relevant effects and the principal objective of the study. Researchers use data on secondary outcomes (secondary end-points) to evaluate additional effects of the intervention. |
| Equipoise standard | 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. |
| Ethics committee | An ethics committee is any committee that is responsible for ethically reviewing health and disability research proposals. Such a committee may be accredited or otherwise; for more information see 'Approved ethics committees' above. |
| Ethics Committee on Assisted Reproductive Technology (ECART) | a ministerial committee that reviews, determines, and monitors applications for assisted reproductive procedures and human reproductive research. |
| Funder | <p>An individual, company, institution or organisation that provides funding for a study. In some cases the funder may delegate responsibility for initiating or managing a research project to investigators.</p> <p>See also 'Sponsor'.</p> <p>In distinguishing between funders and sponsors, relevant considerations include arrangements of access to study data, control over publications, and conflicts of interest.</p> |
| Health and disability ethics committee (HDEC) | An ethics committee established under section 11 of the New Zealand Public Health and Disability Act 2000 and approved by the HRCEC. |
| Health information | Has the meaning given to it by the Health Information Privacy Code 1994 . |
| Health Research Council (HRC) | The agency responsible for managing the New Zealand Government's investment in health research, and for maintaining an ethical and safe health research environment. |
| Health Research Council Ethics Committee (HRCEC) | A committee which provides advice on health research ethical issues and approves HDEC and institutional ethics committees. |
| Health Service Provider | Health service providers include health service workers, nurses, clinicians and any person involved in quality improvement. |
| Human tissue | Has the meaning given to it by the Human Tissue Act 2008 . |
| Indication | A condition for which the use of a certain intervention (eg, a certain medicine) is indicated or appropriate. |

| Term | Definition |
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| Innovative practice | 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. |
| Intervention study | A study in which an investigator controls and studies an intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of that intervention(s). The term 'intervention study' is often used interchangeably with 'experimental study'. Many intervention studies are clinical trials. |
| Investigator | Any investigator on a study who is not the coordinating investigator. This includes investigators who are responsible for the conduct of a study at a given location. A study may have any number of investigators. |
| Investigator's brochure | A document summarising the clinical and other data relating to a new medicine that is relevant to the study of the product in human participants. |
| Locality | A locality is an organisation responsible for a hospital, health centre, surgery or other establishment or facility in New Zealand at or from which the procedures outlined in the protocol of a study are to be conducted. |
| Māori terms | Please see https://Maoridictionary.co.nz/ for definitions of Māori terms. |
| Medical device | has the meaning given to it by the Medicines Act 1981 . |
| Medsafe | New Zealand Medicines and Medical Devices Safety Authority. |
| New medicine | Has the meaning given to it by the Medicines Act 1981 . |
| Non-therapeutic study | A study that examines interventions that do not hold the prospect of direct diagnostic, therapeutic or preventive benefit to the individual study participant. Types of non-therapeutic studies include some phase I trials, bioequivalence studies and bioavailability studies. |
| Observational research | Research in which (in contrast to intervention or experimental studies) no intervention other than the recording, classifying, counting and analysing of data takes place. In observational studies the investigator has no control over study variables and merely observes outcomes. |
| Participant | A person who is enrolled in a study. In some studies, participants are grouped in communities (eg, geographical communities, or organisations such as schools). Some studies may use |

| Term | Definition |
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| <p>Phase I study</p> | <p>participants' data or tissue. Participants may be patients, consumers, or family members and whanau.</p> <p>A study involving the initial administration of a new investigational intervention into humans. Although human pharmacology studies are typically identified as phase I, they may also be later phase studies. Phase I studies usually have non-therapeutic objectives, and may be conducted in healthy volunteer subjects, or in patients with a specific disease (particularly in the case of studies of cytotoxic drugs). Studies in this phase can be open or baseline controlled, or may use randomisation with blinding to improve the validity of observations. Studies conducted in phase I typically involve one or a combination of:</p> <ul style="list-style-type: none"> • estimation of initial safety and tolerability, pharmacokinetics, assessment of pharmacodynamics, and early measurement of drug activity. |
| <p>Phase II study</p> | <p>A study usually considered to start exploring the therapeutic efficacy of an intervention in patients. Initial therapeutic exploratory studies use a variety of study designs, including concurrent controls and comparisons with baseline status. Subsequent phase II studies are usually randomised and use concurrent controls to evaluate the efficacy of an intervention and its safety for a particular therapeutic indication.</p> <p>Studies in phase II are usually conducted in a group of patients who are selected by relatively narrow criteria, leading to a relatively homogeneous population that is closely monitored. One important goal for this phase is to determine the dose(s) and regimen for phase III studies.</p> <p>Additional objectives may include evaluation of potential study end-points, therapeutic regimens (including concomitant medications) and target populations (eg, mild versus severe disease) for further study in phase II or III. Phase II studies are sometimes further categorised as</p> <ul style="list-style-type: none"> • phase IIa studies (where the focus is on assessing dose requirements) <p>or</p> <ul style="list-style-type: none"> • phase IIb studies (which are designed to evaluate efficacy). |
| <p>Phase III study</p> | <p>A study with the primary objective of demonstrating or confirming therapeutic benefit.</p> <p>Phase III studies are designed to confirm the preliminary evidence accumulated in phase II that an intervention is safe and effective for the intended indication and recipient population.</p> |

| Term | Definition |
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| | <p>Studies in phase III may also further explore the dose–response relationship, or investigate the intervention’s use in wider populations, in different stages of disease or in combination with another intervention.</p> <p>For interventions intended to be administered for long periods, studies involving extended exposure to the intervention are usually conducted in phase III, although they may be started in phase II.</p> |
| Phase IV study | <p>A study (other than routine surveillance) performed after an intervention’s approval, related to the approved indication. Phase IV studies are studies that were not considered necessary for approval but can be important for optimising the intervention’s use. They may be of any type of study design, but should have valid scientific objectives.</p> <p>Studies in this phase commonly examine additional drug–drug interaction or the dose–response relationship or safety, or investigate use under the approved indication, such as mortality/morbidity studies and epidemiological studies.</p> |
| Protocol | <p>A description of a study’s objectives, design, methodology, statistical considerations and organisation.</p> <p>The protocol often gives the background and rationale for the trial, but other documents referenced by the protocol may provide these.</p> |
| Qualitative research | <p>Research involving the studied use of empirical materials such as case studies, personal experience, life stories, interviews, observations and cultural texts.</p> |
| Quantitative research | <p>Research involving systematic empirical investigation via statistical, mathematical, or computational techniques.</p> |
| Randomised controlled trial | <p>The general term for a study in which participants are randomly assigned to intervention and control groups to receive or not receive a diagnostic, preventive or therapeutic intervention. Findings in such a study are assessed by comparing rates of disease, death, recovery or other appropriate end-points in the intervention and control groups.</p> |
| Researcher | <p>Increasingly, health research and quality improvement involve responsibilities that are broader, extending to institutions and organisations. The Standards primarily use the term ‘Researcher’ throughout when referring to corresponding responsibilities, however it should be understood that these Standards use the term Researcher broadly, intending to address all those responsible for the conduct of health and disability research, quality improvement</p> |

| Term | Definition |
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| | activities, data and tissue governance, and any other activity described in these Standards. |
| Researcher-initiated research | Researcher-initiated research is research proposed by researchers and without a company or commercial entity taking the role of sponsor. Such research can be conducted by an individual researcher, an institution, a group of institutions, a collaborative study group or a cooperative group. |
| Sponsor | An individual, company, institution or organisation that is responsible for initiating, managing and/or financing a study. This excludes an individual company, institution or organisation that has been requested to provide money for a trial and does not benefit in any way from the results of the trial. See also funder. |
| Standing Committee on Therapeutic Trials (SCOTT) | A standing committee of the HRC whose function is to make recommendations to Medsafe regarding the approval of clinical trials of new medicines under section 30 of the Medicines Act 1981 . |
| Therapeutic study | A study that examines interventions that hold the prospect of direct diagnostic, therapeutic or preventive benefit. |
| Treatment | Any type of intervention that may be studied, including medicines, tests, methods of health care delivery and other health or disability support interventions. |