Overview of this session

- Foundations of Ethics
- Why Research Ethics Matters In New Zealand
- Introducing The Partnership Of Principles
- Overview of NEAC Standards - Highlights
- Looking Forward – Changing Research Ethics Landscape

We have a mix of new and experienced researchers here today, and limited time. We will briefly cover what ethics is and why it matters.

It is important to understand the historic context in which the NEAC standards fit, their purpose and, of course, how to use them.

We have a series of case studies that our team has developed. These break up the presentation aspects of the day, and provide insight into how the Standards might work in practice. It is not about solving all of the problems we present, but we do ask that you think what the ethical issues in the case studies are, and what possible solutions could be.
Established in 2001 the National Ethics Advisory Committee (NEAC) is an:

Independent advisor to the Minister of Health

NEAC’s statutory functions, are not limited to, but include

- advising the Minister on ethical issues on any health and disability matters
- determining nationally consistent ethical standards across the health sector.

The national standards are what we are here today to discuss.
Members of NEAC

- Neil Pickering: Health Research Council nominee
- Maureen Holdaway: Health researcher
- Wayne Miles: Health professional
- Kahu McClintock: Māori member
- Liz Richards: Community/consumer
- Hope Tupara: Health professional
- Dana Wensley: Lawyer
- Gordon Jackman: Disability representative
- Mary-Anne Woodnorth: Health researcher

Prior members of NEAC
- Monique Jonas
- Martin Wilkinson
- Julian Crane
- Adriana Gunder
I want to thank everybody who has contributed to these National Ethical Standards. It was a long journey to get them finished, though our work in ethics is never truly complete. These Standards will be updated continually, as we recognise that ethics is a living and moving concept.

**Members of the National Ethics Advisory Committee**

**Members of the Ministry of Health Working Group – Kate O Connor**

*In particular, the work of Barry Smith, who passed away prior to the publication of these Standards. Barry’s contribution was invaluable to their development.*

**Ministry of Health Secretariat**

HQSC

165+ submitters
Researchers and government agencies
Foundations of ethics
Western Ethics and Bioethics

- **Ethics** seeks to address philosophical questions about morality.
- **Bioethics** concerns ethical issues that arise in relationships among life sciences, biotechnology, medicine, politics, law, philosophy and theology.
- **Health research ethics** refers to ethical conduct in research, as well as the protection of research participants.

Ethics – also known as moral philosophy – seeks to address philosophical questions about morality.

When most people think of ethics (or morals), they think of rules for distinguishing between right and wrong, such as the Golden Rule ("Do unto others as you would have them do unto you"), a code of professional conduct like the Hippocratic Oath ("First of all, do no harm"), or a religious creed like the Ten Commandments ("Thou Shalt not kill...").

Ethical norms, such as you should not kill, are so ubiquitous, or obvious, that one might be tempted to regard them as simple commonsense. On the other hand, if morality were nothing more than commonsense, then why are there so many ethical disputes and issues in our society?

One plausible explanation of these disagreements is that all people recognize some common ethical norms but interpret, apply, and balance them in different ways in light of their own values and life experiences. For example, two people could agree that murder is wrong but disagree about
the morality of abortion because they have different understandings of what it means to be a human being.

**Ethics is about identifying ways, using frameworks, of which there are many, to understand moral problems, or disagreements.**

**Bioethics** is a subset of ethics, involving the study of the ethical issues emerging from advances in biology and medicine. Bioethics concerns ethical issues that arise in relationships among life sciences, biotechnology, medicine, politics, law, philosophy and theology.

Finally, health research ethics is about navigating ethical tensions inherent when conducting research with humans.

Where did research ethics come from? In the west, it was born from tragedy.

Research with human beings has improved healthcare steadily since the first clinical trials in the early 1930s. Our standards of care, developed and better understood through research, enable many to lead healthy lives.

However, the history of medical research is marred by exploitative and dubious human experimentation. In the wake of each disaster have come new and improved rules, protections and expectations for conducting research with human beings.
To be able to appreciate where you are at any point in time we must acknowledge and learn from the past, both good and bad….

or we are likely to repeat it.

National Archives Collection of World War II War Crimes Records, 1933 – 1950

This is an image of 16 doctors and administrators who were found guilty of "willing participation in the systematic torture, mutilation, and killing of prisoners in experiments."

During the war atrocities were conducted on thousands of prisoners in the name of scientific knowledge. In particular, disabled people were targeted and exploited, another feature addressed in the NEAC standards.

The trials highlighted highly unethical medical research conducted by Nazi doctors on their many captives in the concentration camps in World War II.

Some examples are experiments on twins, disabled people, freezing experiments, head injury experiments, bone, muscle and nerve transplantation experiments and sterilization practices.

In 1947, after World War II, at the Nuremberg trials, the Nuremberg Code for ethical conduct of research involving human subjects was developed – marking the first international code of research ethics.
But having a document published with rules and standards does not automatically result in ethical research. Even with the Nuremberg Code established as an international document in 1947 – large scale unethical research, with US government support and funding, was conducted.

In 1932, the Public Health Service, working with the Tuskegee Institute, began a study to record the natural history of syphilis in hopes of justifying treatment programs for African americans. It was called the "Tuskegee Study of Untreated Syphilis in the Negro Male."

The study initially involved 600 black men – 399 with syphilis, 201 who did not have the disease.
Tuskegee – Unethical Research

- No evidence that researchers had informed them of the study or its real purpose.
- Never given adequate treatment for their disease (halfway through the study a treatment was developed but was not given to participants)
- Never given the choice of quitting the study
- Of the 399 participants with syphilis:
  - 28 men died of syphilis
  - 100 died of related complications
  - 40 wives were infected
  - 19 of their children born with congenital syphilis.

Researchers told the men they were being treated for "bad blood," a local term used to describe several ailments, including syphilis, anaemia, and fatigue. In truth, they did not receive the proper treatment needed to cure their illness. In fact, during the study, penicillin was developed as a cure, but not given to participants. In exchange for taking part in the study, the men received free medical exams, free meals, and burial insurance.

- No evidence that researchers had informed them of the study or its real purpose.
- Never given adequate treatment for their disease (halfway through the study a treatment was developed but was not given to participants)
- Never given the choice of quitting the study
- Of the 399 participants with syphilis:
  - 28 men died of syphilis
  - 100 died of related complications
  - 40 wives were infected
  - 19 of their children born with congenital syphilis.
Tuskegee – Consequences

- The study ended in 1972, after 40 years – only after an Associated Press story about the Tuskegee Study caused a public outcry that led the Assistant Secretary for Health and Scientific Affairs to appoint an Ad Hoc Advisory Panel to review the study.

- As a result of this trial the US enacted the National Research Act which established…

- The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

- Developed the Belmont Report – the leading US research ethics report of the time.

The study ended in 1972, after 40 years – only after an Associated Press story about the Tuskegee Study caused a public outcry that led the Assistant Secretary for Health and Scientific Affairs to appoint an Ad Hoc Advisory Panel to review the study.

As a result of this trial the US enacted the

- National Research Act which established…

- The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- Developed the Belmont Report – the leading US research ethics report of the time.
Examples of international codified universal principles

- International Ethical Guidelines for Health-related Research Involving Human
- Declaration of Helsinki
- Nuremberg Code
- CIOMS 2017

Example of a ‘universal’ principle: Autonomy - the ability of the person to make their own decisions ➔ informed consent etc.

There are countless examples of unethical health research that lead to improvements, reactions and new codes or standards.

A few examples are up on the screen, and they all have something in common. They purport that universal principles should guide practice in order to conduct ethical research, i.e. to protect research participants, while also generating ‘good’.

These principles are adapted to form a range of internationally recognised codes such as the Nuremberg Code, the Declaration of Helsinki and the Belmont Report.

In New Zealand, we also adopt these ‘universal’ principles, they feature in documents such as the Code of Health and Disability Services Consumers’ Rights 1996 and the Health Information Privacy Code 1994.

The most recent being the CIOMS international ethical guidelines. CIOMS mission is to advance public health through guidance on health research
including ethics, medical product development and safety.

This document also brands itself as universal, and while these guidelines represent many gold standards in ethical thinking, particularly due to the resources and expertise that went into this document, when developing it they have no requirement to adhere to local laws or cultures, and as such are useful as a starting point, but may not apply to ethics, culture or law in New Zealand.
Ethics in New Zealand has another history, finding morality through Tikanga. The primary indigenous reference for Māori values and ethics are the creation stories which highlight specific relationships deemed fundamental to the sustainability of life. These relationships are embedded as kawa (primary values) and provide the foundation for the establishment of tikanga.

Tikanga are locally specific practices that aim to enhance these relationships and ensure the preservation of mana (justice and equity, reflected through power and authority). As the environment changes or new situations arise, tikanga are enacted or adapted to provide context-specific responses.

Kawa and tikanga provide the primary interface for accessing repositories of cultural knowledge and experience that can be used to inform ethical deliberations.

Tikanga also provides a framework through which Māori can actively engage with ethical issues and consider the effect research may have on their values or relationships.
Creation stories give people a way of looking at their world. These stories tell us about individuals acting in particular ways and securing their position in the world. They stand, therefore, as a model for individual and collective behaviour and aspirations.

Legendary heroes act as exemplars of human potential. By capturing the sun, entering the underworld, or fishing up an island, Māui represents the character of the individual who can bring about change and development in a community. The ascent of Tāne through the 12 heavens to obtain the baskets of knowledge symbolises an individual striving toward insight and understanding.

Many of the gods who represent the divine character or spirit of an aspect of the natural world, such as Rongomātāne of cultivated foods, are included in a genealogical chart, the recitation of which establishes a fundamental relationship between humans and the natural world.
The Treaty of Waitangi

- **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.

A universal approach to ethical principles, may not take into account the extent to which cultural traditions influence and enhance ethical study and practice. For example, creation stories are a primary reference for Māori ethics. These stories have often highlighted the nature of relationships, how the world is perceived, and the way in which people interact with each other. These interactions further inform tikanga Māori, and the components of tikanga (such as the values of tapu and noa, and relationships to whakapapa and wairua) which in turn provide a framework through which Māori can actively engage with ethical issues, determine rights and wrongs, and analyse harms and benefits (Hudson et al 2010).

In the past, Some have expressed concerns that if New Zealand adopts a ‘universal research ethic’, specific cultural issues and the existence of a Māori research ethic may be overlooked (Cram 2003; Hudson 2004).

As outlined, historically, ethics have often been constructed through Western frameworks that may not necessarily be transferrable to other contexts and times (Munshi et al 2011; Tupara 2011). Furthermore, Western ethical
research perspectives have tended to focus on legal requirements and institutional codes of ethics which commonly centre on ensuring benefits and fairness to individuals and protecting individual rights.

Therefore, researchers design documents such as information sheets for prospective participants, privacy statements and consent forms. This focus on the individual rather than on the collective, and written documents rather than on oral statements, may not adequately address ethical principles for Māori, and has been described as unsafe for whānau (Chetwin et al 2000).
Indeed, indigenous populations have long traditions of conducting their own research and experiments, and developing their own ethical guidance.

Yet both historical and recent research on these communities, conducted by Western researchers with a poor understanding of indigenous ethical principles, has strengthened the sense of disempowerment, exploitation, and a lack of regard for indigenous cultural values, beliefs and knowledge systems.

In New Zealand, Māori have been the subject of research where the objectives, methodology and outcomes have failed to address many issues for Māori including power, equity and the validity of alternative understanding of knowledge.

However, social changes over the past 30 years have both increased awareness of the value that research contributes to development and health equity, and led to a reconstruction of what is considered ethical research practice within Māori communities. The Māori research community has
worked to develop more respectful research relationships and to become agents of research that is grounded in Māori concepts, values and priorities.

In the past, New Zealand’s system of ethical review has also been challenged for not adequately considering Māori interests and ethical perspectives, including the rights of the collective, principles of tikanga and mātauranga Māori, and culturally significant ethical boundaries.

Our work with the NEAC standards we have aimed to address these criticisms, and while it is but one step forward, the Standards represent the first time New Zealand has joined Maori bioethics together with the western bioethics – our partnership of principles. We also have worked to integrate much of the work that has been done by Maori to date, including He Tangata Kei Tua, Te Mata Ira and Maori data sovereignty principles.
I have given you a rapid overview of different sources of ethical principles. Now I turn to why we need ethics committees and why research ethics matters.
New Zealand has had its share of medical disasters that have shaped our current ethical review environment. Each case involved widespread public attention, and resulted in reform and improvement of research regulation.

In the interests of time I will only briefly two of these cases.
The Unfortunate Experiment
The Cartwright Inquiry

- Associate Professor Herbert Green (gynecologist) had been intentionally undertreating women with cervical cancer and experimenting on his patients without their consent or proper approval. He was publishing this work in journals.

- Two prominent women's health advocates and writers (Sandra Coney and Phillida Bunkle) published an expose relating to publications by Dr Green in relation to treatment of CIS (carcinoma in situ) in Metro Magazine in June 1987.

- The Cartwright Inquiry was a Commission of Inquiry held in New Zealand from 1987 – 1988 to investigate the alleged malpractice of Associate Professor Herbert Green. The inquiry was headed by then District Court Judge Silvia Cartwright.

- The Inquiry also exposed other unethical practices:
  - Cervical smears were taken from newborn baby girls without their parents’ consent.
  - Exposed the hospital's practice of teaching vaginal examinations and IUD insertions on unconsenting women anaesthetised for operations.
  - The Inquiry revealed that several doctors in the hospital had tried to stop Green's studies but the hospital and hospital board hierarchy had declined to take action.

New Zealanders had their Tuskegee moment in June 1987, when *Metro* magazine published the investigative report “An Unfortunate Experiment at National Women’s.” According to the report, women with cervical cancer in situ had been deceived and mistreated for years at a prestigious Auckland hospital. This revelation led to an official government inquiry, six months of public hearings, and, most importantly, far-reaching reforms that have effectively prevented any further such abuses.

Associate Professor Herbert Green had been intentionally undertreating women with cervical cancer and experimenting on his patients without their consent or proper approval. He was also publishing this work in journals.

The Inquiry also exposed other unethical practices:
Cervical smears were taken from newborn baby girls without their parents' consent. Exposed the hospital's practice of teaching vaginal examinations and IUD insertions on unconsenting women anaesthetised for operations.

The Inquiry revealed that several doctors in the hospital had tried to stop Green's studies but the hospital and hospital board hierarchy had declined to take action.

Additional info:

A 1984 medical paper[1] by a colposcopist, pathologist, gynaecologist and a statistician, described a study of 948 woman who had been diagnosed with carcinoma in situ (CIS) at New Zealand's National Women's Hospital from 1955 to 1976. The authors of the paper divided the women who had presented at the hospital with a positive smear into two groups – those whose smears had reverted to normal after two years and those who continued to have a positive smear, regardless of treatment.

Those who continued to have a positive smear had a higher rate of invasion to cervical cancer, confirming the author's preference for early intervention. There was by the 1980s an extensive amount of international literature questioning whether early intervention was necessary or was over-treatment, causing more harm than good.

Two prominent women's health advocates and writers, Sandra Coney and Phillida Bunkle, published an expose relating to treatment of CIS (carcinoma in situ) in Metro Magazine in June 1987,[3] titling it the "Unfortunate Experiment".

Coney and Bunkle misinterpreted the 1984 paper as describing a prospective rather than a retrospective study.[5] This expose of supposed mistreatment led to widespread public outcry and the then Minister of Health, Michael Bassett calling an inquiry.

The Cartwright Inquiry was a Commission of Inquiry held in New Zealand from 1987 – 1988. It was commissioned by the then Minister of Health, Michael Bassett to investigate the alleged malpractice of Associate Professor Herbert Green, a gynaecology and obstetrics specialist. The inquiry was headed by then District Court Judge Silvia Cartwright.
The Unfortunate Experiment
The Cartwright Inquiry

- District Court Judge Silvia Cartwright concluded that Green’s work varied significantly from what was considered good practice and put his patients at risk.

  - The Office of Health And Disability Commissioner was established under the HDC Act in 1994
  - The Code of Health and Disability Services Consumers’ Rights which enshrined informed consent, in force from 1996.
  - Teaching practice was changed at National Women’s Hospital and Auckland Medical School to conform to international practice.
  - Independent health ethics committees were set up throughout New Zealand
  - A national cervical screening programme was established.

Like low-budget horror movies, medical research scandals tend to follow a predictable script. The ambitious researchers are blinded by hubris, while the research subjects are vulnerable and powerless. Medical insiders are aware of the abuses taking place, but few speak out. If they do, they are crushed by functionaries in suits whose only concern is protecting the reputation of the institution. Eventually the research abuses come to light, at which point the audience gasps and wonders: How could this have possibly happened?

District Court Judge Silvia Cartwright concluded that Green’s work varied significantly from what was considered good practice and put his patients at risk.

The Office of Health And Disability Commissioner was established under the HDC Act in 1994 the Code of Health and Disability Services Consumers' Rights which enshrined informed consent, in force from 1996. Teaching practice was changed at National Women's Hospital and Auckland Medical School to conform to international practice. 

**Independent health ethics committees were set up throughout New Zealand**

A national cervical screening programme was established.
A government ordered inquiry into cervical screening in the Gisborne region was initiated after it was discovered that a local laboratory had failed to identify hundreds of abnormal smears.

The Inquiry examined the practices of pathologist Dr Michael Bottrill, who owned the laboratory and was responsible for reading the smears.

- His laboratory found 0.53 high-grade abnormalities compared with a national average of 1%.
- Once Dr Bottrill retired in 1996, the rate of high-grade abnormalities found jumped to 1.71%.

22,978 slides, belonging to 12,108 women who had had smears taken in the region between 1991 and 1996, were re-read.

- 9,584 women had all their smears originally reported and re-read as normal.
- However a large number of women (1,997) were advised of abnormalities, many of which were previously un-reported.
taken in the region between 1991 and 1996, were re-read. 9,584 women had all their smears originally reported and re-read as normal. However a large number of women (1,997) were advised of abnormalities, many of which were previously un-reported
Gisborne cervical smear inquiry

- It was the persistent efforts of one woman that finally brought the issue in Gisborne to light.
  - Between 1990 and 1994 four of her smear tests were misreported.
  - The first of three smears should have been reported as revealing high-grade intraepithelial lesions and the fourth as invasive cancer.
  - Finally she was diagnosed with cervical cancer by a gynaecologist and had a radical hysterectomy and extensive radiation therapy.
  - By the time she had treatment, her prognosis was a 40% chance of the cancer recurring or metastasising, whereas had she been treated when the high-grade abnormalities were first detected, her chance of cure would have been virtually 100%.

It was the persistent efforts of one woman that finally brought the issue in Gisborne to light.

Between 1990 and 1994 four of her smear tests were misreported. The first of three smears should have been reported as revealing high-grade intraepithelial lesions and the fourth as invasive cancer. Finally she was diagnosed with cervical cancer by a gynaecologist and had a radical hysterectomy and extensive radiation therapy. By the time she had treatment, her prognosis was a 40% chance of the cancer recurring or metastasising, whereas
had she been treated when the high-grade abnormalities were first detected, her change of cure would have been virtually 100%.
Gisborne cervical smear inquiry

- The Gisborne Inquiry delivered 46 recommendations to ensure the safety and quality of the National Cervical Screening Programme.

- The committee concluded that there was ‘ample evidence’ of Dr Bottrill’s under-reporting with a wide discrepancy between the results of the Gisborne lab and the Australian labs used for the reread.

- At least 16 women had developed cancer because of the under-reporting.

- The committee concluded that Dr Bottrill used deficient practices in his lab, was not accredited and lacked quality control, but that the National Cervical Screening Programme was responsible for not detecting his failure.

- This case shaped the need to report incidental findings and shows what can happen when there are no reporting plans in place for research.

- It also highlights the ethics of, and need for, quality improvement, as outlined in the NEAC standards.

The Gisborne Inquiry delivered 46 recommendations to ensure the safety and quality of the National Cervical Screening Programme.

The committee concluded that there was ‘ample evidence’ of Dr Bottrill’s under-reporting with a wide discrepancy between the results of the Gisborne lab and the Australian labs used for the reread.

At least 16 women had developed cancer because of the under-reporting.

The committee concluded that Dr Bottrill used deficient practices in his lab, was not accredited and lacked quality control, but that the National Cervical Screening Programme was responsible for not detecting his failure.

This case shaped the need to report incidental findings and shows what can happen when there are no reporting plans in place for research.
It also recognizes the need to conduct quality improvement, as outlined in the NEAC standards
I will now turn to the Standards, their place in history and the future of ethics.
The first reason we updated the existing documents was that they were outdated. Research, science, technology and ethics moves at a rapid pace. Though these two texts were slightly updated in 2012, the present iteration represents the first major reconsideration of the Standards since 2009.

The 2012 Guidelines are two separate documents, the Ethical Guidelines on Intervention Studies and Ethical Guidelines on Observational Studies. The revised Standards merge the two texts into one cohesive document, making it much easier for ethics committees and researchers to use.

Substantial gaps in guidance (based on 2009 work)
Confusing layout, two separate documents
In print – unable to be changed
Much of the guidance put into appendices at the end of the document that were not formally standards
Our National Ethical Standards are not a reaction to tragedy.

They are responding to an increasingly complex ethical landscape, and reflect ethics that represent New Zealand values and culture.

The Standards aim to address equity issues in health research which is a core purpose of the Health Research Strategy 2017.

The Standards will be a living document that is online only and can be updated easily.

We are building feedback loops and stronger relationships between ethics committees 'on the ground', researchers and national ethics committees.

Our new ethical standards form part of an overhaul of the New Zealand research landscape.

Part of my role involves implementation of the New Zealand Health Research Strategy 2017. When developing the strategy, ethics was put on the map – and recognised as a core part of health research. The Standards are the first part of strengthening the new Zealand ethics landscape, and importantly, will address equity issues in health research and improve health outcomes overall, which is a key outcome of the Health Research Strategy.

We also wanted to move away from developing standards that become outdated or are not updated for years, so in order to keep the Standards current as technology and methodologies advance, the Standards are an online only living document can be updated easily.

We are developing feedback loops between researchers, ethics committees and our national bioethics policy committees. Part of this is reflected in
having this meeting today. Other mechanisms are through the Ministry Secretariat feeding back information from the HDECs to NEAC, and from HDEC Chairs to the Ministry. Our new IT systems will support greater engagement with researchers.
Addressing the tension

The NEAC Ethical Standards fulfil a range of functions…they

- give researchers and ethics committees the language to and engage in ethical discussion
- provide tools to know when there may be ethical issues raised in research
- provide guidance on how to mitigate and or manage ethical issues
- …and if you print them out they will make a good door stop.

Having been at many ethics committee meetings, often researchers and ethics committees misunderstand each other or talk past each other. Our hope is that our ethical standards will facilitate meaningful ethical dialogue and increase the understanding of why an ethics committee may think there is a risk in a project, as well as giving researchers the tools to justify and make their case.

The document contains tables, explanations of Standards and will facilitate better dialogue.

Some examples are the benefit and harms chapter, that includes language that researchers can use to communicate the study risks to ethics committees, and its benefits, to justify it being conducted.
Conflict, tensions and ethical justifications

- The Standards enable systematic analysis and resolution of conflicts through an evidence-based application of Te Ara Tika and Bioethical principles.
- (all) health research and QI will have conflicts and require ethical consideration
- The ethical significance of key health issues can be understood, analysed and appropriate solutions can be developed.

A bioethics framework provides for a systematic analysis and resolution of conflicts through an evidence-based application of Te Ara Tika and Bioethical principles.

You can do this by asking yourself the questions under each principle about your own studies.

Bioethics provides a framework of values and principles, through which the ethical significance of key health issues can be understood, analysed and appropriate solutions can be developed.

Expand here on how both have different angles on the same issue, what causes tensions – funding, complex.
Framework for Analysing the Ethics of a Research Study

- Although codes, policies, and principals are very important and useful, like any set of rules, they do not cover every situation, they often conflict, and they require considerable interpretation.

- Researchers must learn how to interpret, assess, and apply various research rules and how to make decisions and to act ethically in various situations.”

  (Resnik 2015)

A little later on today our team will introduce a framework that can be used with the Standards to consider ethical issues in health research. We are encouraging researchers to do this from the onset of design, not at the time of writing the ethics application.

This is also useful as while their size may suggest otherwise, the NEAC Standards will not and do not cover every possible ethical issue in research. Sometimes you will need to make principled arguments, where specific Standards are not available.
This highlights session is primarily to generate discussion on how researchers might implement new concepts or standards in the NEAC document.

This session is broken into parts – we will come back to it after lunch and will get through as much as we can during the morning session.
This session will cover

- Impact on researchers – how much has changed?
- What are Standards? Were there Standards before?
- Highlights of changes, and themes of the changing ethics landscape
NEAC Highlights
### Some key decisions

- The Standards will have a strong educative function (consequence – they are quite long!)
- The Standards apply to all health research and disability research
- The Standards will cover quality improvement, innovative practice and health systems research
- The Standards apply whether or not research or quality improvement activities require review by an ethics committee
- The Standards take a risk-based approach to ethical oversight, for example
  - If secondary use requires consultation or not,
  - The degree of data governance requirements,
  - The complexity of informed consent processes
- Ethical review should be proportionate to the risk proposed by the activity
- Online only – soon to be an HTML5 website

The Standards will have a strong educative function (consequence – they are quite long!)
The Standards apply to all health research and disability research
The Standards will cover quality improvement, innovative practice and health systems research
The Standards apply whether or not research or quality improvement activities require review by an ethics committee
The Standards take a risk-based approach to ethical oversight, for example
If secondary use requires consultation or not, 
The degree of data governance requirements, 
The complexity of informed consent processes

Ethical review should be proportionate to the risk proposed by the activity
New Structure: Standards and Commentary

3.3 Research design must demonstrate cultural rigour in order to meet ethical requirements.

3.3a 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.

3.3b 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?

3.3c 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?

Here is one example of the structure of the standards – we have subheadings followed by numbered standards and commentary. The introductions and commentary fulfils the educative function of the standards, and brings clarity to the intention behind standards.

For example:

3.3a 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.

3.3b 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?

3.3c 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?

This particular example was developed by Barry.
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.

In the data chapter we have different considerations for institutions, as well as individual researchers.
What is new?

The following is a very brief overview of more explicit standards and guidance. These standards are not necessarily new requirements, but their intent and how to achieve them is set out much more clearly than before. I will also spotlight some challenges that we will need to consider as we continue to strengthen the NZ research landscape.
New (entire) Chapters

- Partnership of Principles
- Disability research
- Research benefits and harms
- Ethical management of vulnerability
- Human tissue and Biobanks
- Health data and new technologies
- Research with stem cells and reprogrammed cells
- Quality Improvement
New guidance, concepts or themes

- New guidance on determining if an activity is research
- Consulting and engaging earlier
- Adding an equity lens to health research
- Modifications to informed consent
- Health data governance and management
- Stronger justification for waiver to data and tissue
- Health systems research ethics
- Comparative effectiveness research (lower risk clinical trials)
- Supported decision making
After we wind down the road show we will turn to operational changes for the remainder of the year.

### HDEC Operational Changes

- New templates for informed consent
- New application forms that are tailored to research type and risk
- More consistent guidance for and engagement with researchers
Taking into account the historical separation of Maori and Western bioethics, our national standards set out two sets of principles that collectively form the basis for these standards: Te Ara Tika principles and bioethics principles. This is something unique to New Zealand, and enriches our ethical debate.

This is also one of the most major differences between the old and new Standards.

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’ 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.

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.
I will now expand on what these principles mean, and may be interpreted by ethics committees and researchers.
Will the chosen design achieve proposed outcomes?
What are the benefits for participants and communities?
Will it bring about positive change?
Have communities been involved?
  - For example in determining that the research question(s) are important, and reflecting on the ethical issues associated with the study?

Tika refers to what is right and what is good for any particular situation. Tika highlights the value engagement, of asking communities about which research questions are important.

Although the quality of the information produced by research depends critically on the scientific value of a study, scientific value alone does not make a study socially valuable. For example, a study can be rigorously designed but lack social value when the research question has been successfully addressed in prior research. Or alternatively, if the study question is not appropriate for the community, it may be well designed but not ethical to conduct.
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 value of the answer to the scientific question posed by the study must be worth the risk, inconvenience, and resources committed to it.

In order to be ethically permissible, health-related research with humans, including research with samples of human tissue or data, must have social value. The scientific and social value of research can be difficult to quantify, but it is generally grounded in three factors: the quality of the information to be produced, its relevance to significant health problems, and its contribution to the creation or evaluation of interventions, policies, or practices that promote individual or
public health.

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.
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.

What relationships are identified in the study? Are participants being respected? Have researchers considered privacy and confidentiality to prevent harmful effects from disclosure of information? Does the study consider cultural and social responsibilities? Were the goals and benefits of the study determined with those who are being studied? Does the study present opportunities to empower research partnerships?
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.

The potential individual benefits and risks of research must be evaluated in a two-step process. First, the potential individual benefits and risks of each individual research intervention or procedure in the study must be evaluated.

In a second step, the aggregate risks and potential individual benefits of the entire study must be assessed and must be considered appropriate.

The aggregate risks of all research interventions or procedures in a study
must be considered appropriate in light of the potential individual benefits to participants and the scientific social value of the research, including for communities.
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.

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 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.
Respect for people

- Are potential participant’s providing informed consent?
- If they are not, what is the rationale and justification for enrolling them?
- Are there modifications to the informed consent process? Are those modifications necessary?
- Do any potential participants have diminished capacity? Are there increased support options in place?
- Do participants have the option of withdrawing?
- Are study results returned to the participants in an accessible format?

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

- Are benefits and burdens of study participation fairly distributed across participants? What about study populations?
- Does the study have the possibility of reducing or increasing inequities? And if so, what plans are there to increase the chance of benefits being realized, and reduce risk of increasing health disparity?
- Does the study unfairly exclude any populations?
- Is the study designed to obtain knowledge that benefits the class of persons of which the subjects are representative?

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.

Studies should be designed to obtain knowledge that benefits the class of persons of which the subjects are representative: the class of persons bearing the burden should receive an appropriate benefit, and the class primarily intended to benefit should bear a fair proportion of the risks and burdens of the study.

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.
Looking forward
Equity is found in both sets of ethical principles and it aligns with and is closely related to human rights principles, and particularly the right to health, that is the enjoyment of the highest attainable standard of physical and mental health. It has been a key focus in a number of key health research documents, driven primarily by the Health Research Strategy.
What is equity?

- ‘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 activities.

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).

‘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 activities.**
Two examples of areas of importance that are recognised are inequity with people who have disabilities, and between Māori and Non-Maori.

There are significant inequalities in health status between Māori and non-Māori (Ajwani et al 2003). Researchers (Jones 2001; Arroll et al 2002; Bramley et al 2004; Reid and Robson 2007) have identified some of the reasons for these inequalities as:

- differential access to the determinants of good health (such as economic security, good-quality housing, safe and secure employment, good-quality education)
- differential access to health and disability services
- differences in the quality of care received.

These persistent and significant health inequalities between Māori and other New Zealanders have been described as an ongoing breach of the Treaty of Waitangi and as avoidable, unethical and unjust (Whitehead 1990; Woodward and Kawachi 2000; Reid et al 2000; Reid and Robson 2007).
This is a further argument supporting a focus on Māori health aspirations in the ethical review of all health research. An important step in addressing inequalities is to identify them, which is only possible through consistently collecting and analysing complete and accurate information.

The appropriate collection of ethnicity data, and the source of comparative data used can influence the outcome of research, research recommendations, and the ability for research to contribute to improving Māori health outcomes and reducing inequalities (Cormack and Harris 2009).
Another trend in health research ethics, driven by academics and researchers in Australia through the Australian Clinical Trials Alliance, is the increased importance of consumer and patient engagement.

Source: INVOLVE UK 2008
Our changing relationship with the public

Why involve consumers in research?

- ensures issues important to consumers are identified and prioritised
- different perspective
- help disseminate research results into broader community
- help translate research findings into clinical practice
- help implement research findings within health service delivery
- essential requirement of grant applications, accreditation, reporting

There are different levels of involvement. Increased involvement is well understood in disability research, for example.

There are different Types of consumers, and each has a role to play in the design and implementation of research.

**Individuals with personal experience and motivation**
Prior experience in consumer engagement not needed
Helpful for focus groups, working groups

**Expert consumers**
High-level expertise
Participate on organisational boards, advisory committees, major projects

**Why involve consumers in research?**
- ensures issues important to consumers are identified and prioritised
- different perspectives
• help disseminate research results into broader community
• help translate research findings into clinical practice
• help implement research findings within health service delivery
• Increasingly an essential requirement of grant applications, accreditation, reporting

Our changing relationship with the public

How consumers can be involved in research?

- Identifying research priorities
- Planning and design of research
- Assisting with the conduct of research
- Improving participant information, surveys, questionnaires
- Contributing to the evaluation of research results
- Disseminating research findings
- Not simply recruiting patients as participants in clinical trials

How consumers can be involved in research

- Identifying research priorities
- Planning and design of research
- Assisting with the conduct of research
- Improving participant information, surveys, questionnaires – this is particularly key.
- Contributing to the evaluation of research results
- Disseminating research findings
- Not simply recruiting patients as participants in clinical trials

Finding consumers for research

- Ask patients and families from your clinical practice
- Ask colleagues, nursing and allied health staff to contribute names
- Advertise for volunteers
- Approach relevant research and consumer groups and organisations
- Hospital consumer groups
This Prioritisation Framework was developed as part of the implementation of the New Zealand Health Research Strategy 2017–2027 (NZHRS)1.

**What is the purpose of this framework?**

The purpose of this Prioritisation Framework is to:

+ Unite health research stakeholders – funders, research providers, research teams, and communities – to drive high-level health and social outcomes that health research can achieve

+ Identify areas for research focus and infrastructure needs

+ Prioritise how and why health research needs to be done in New Zealand to best deliver on Health Research

I strongly recommend reviewing this document to see the direction we are taking health research in New Zealand, from an ethics perspective, funder
perspective and research conduct perspective.
The pursuit of a more ethical science has come to be associated with building trust by creating transparent processes, inclusive participation and openness to uncertainty, as opposed to distinguishing between ‘is’ and ‘ought’.

The implication of this new model is that the most ethical science is the most sociable one, and thus that scientific excellence depends on greater inclusivity. **We are better together — we must all be ethicists now.**

Bioethics evolves, as does any other branch of knowledge. We need to continue building trust, and strengthen relationships between researchers, communities, policy makers and institutions.
Summary

- Ethics is about navigating tensions and conflicts between principles and values
- Ethics and the research environment is always changing
- Ethics committees and researchers must work together to confirm each case of health research to:
  - Determine that it is a good thing to do, for individuals and for future people
  - Ensure it is being done in the best way
- The NEAC Standards in conjunction with upcoming operational changes will support ethical decision making, consistency and research excellence.
- Today we will highlight further aspects of the Standards and apply them to cases, sharing perspectives, values and finding common ground.
He waka eke noa
A canoe which we are all in with no exception

When we conducted public consultation on the standards we opened the sessions with this proverb, recognising the importance of ethics as the foundation of health and wellbeing. I want to reiterate that here today.
Thank you
This highlights session is primarily to generate discussion on how researchers might implement new concepts or standards in the NEAC document.

We have selected a few examples of chapters but are happy to take questions as well.
New (entire) Chapters

- Partnership of Principles
- Disability research
- Research benefits and harms
- Ethical management of vulnerability
- Human tissue and Biobanks
- Health data and new technologies
- Research with stem cells and reprogrammed cells
- Quality Improvement
New guidance, concepts or themes

- New guidance on determining if an activity is research
- Consulting and engaging earlier
- Adding an equity lens to health research
- Modifications to informed consent
- Health data governance and management
- Stronger justification for waiver to data and tissue
- Health systems research ethics
- Comparative effectiveness research (lower risk clinical trials)
- Supported decision making
Significant efforts have also been made to reflect the aspirations and values of the disability community, recognizing the important distinction between ill-health and disability, and trying to reflect ethical distinctions.

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; 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.
Key guidance on…

- Distinguishing disability research from health research involving disabled people
- Study design and consultation
- Informed consent and facilitating participation
- Disability research data
- Disabled people as researchers


During the public consultation NEAC heard loud and clear that we needed a lot more work on disability research with more coverage for consideration of disabled people, disabled researchers and for disability research. We knew we had more work to do in this area. The Ministry hosted a workshop, assisted by Hilary Stace, that was very well attended from the diverse group of people interested in disability research, and a range of consumers where we asked people to register their interest in developing this chapter of the standards to ensure the Standards had input from disabled people and disability researchers.

Academics and stakeholders were among those invited, and the day consisted of talks by the former’s work in the field, with time also set aside for group discussion. The attendees’ comments proved very useful for the Secretariat in developing a final version of the chapter (a talking-point skeleton had been produced from a literature review prior to the meeting) and resulted in strong practical guidance for research both involving and initiated by disabled people. A valuable point of difference provided by the workshop was high-level nuance on the concept of disability, on which commentary has been made in the Standards.

We wanted people to have the opportunity to freely contribute so the workshop itself was left fairly unstructured apart from a few key themes about how the standards
could be structured to focus on the core values of disabled people as participants, disabled people as researchers and key principles, concepts and values.

What came out of this session was the development of a new section specifically on disability that was perfected via email following the workshop.

Participants were complimentary of how the workshop was managed and approved of having disabled peoples' voices heard when generating ethical guidance for disability research. This was best evidenced by news that Victoria University of Wellington is publishing an academic article on the process undertaken by NEAC and the Ministry of Health in this area, which we are all really proud of.
### What is ‘disability’?

<table>
<thead>
<tr>
<th>The Social Model</th>
<th>The Medical Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disability as imposed by an exclusive society</td>
<td>Disability as bodily (physical or mental) impairment</td>
</tr>
<tr>
<td>Emphasis on overcoming social barriers</td>
<td>Medical or rehabilitative by nature</td>
</tr>
<tr>
<td>High level of reciprocity in research process</td>
<td>Targets novel interventions or ‘cures’</td>
</tr>
<tr>
<td>Focus on society</td>
<td>Focus on the individual</td>
</tr>
</tbody>
</table>

“…social potential [as] not dependent on correcting the disabled body, but instead made possible through institutional and material change”

- Bess Williamson

In these new standards we talk about distinguishing disability research from health research involving disabled people, and the educative function of the standards is to explain 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.

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, we knew it was important to provide specific guidance on the latter.
Study design and consultation

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’ bias, and improve the overall efficacy of the study.

5.5 Researchers should consider ways in which disabled people can be included in their research strategy, 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.

“Nothing about us, without us.”

Our new standards give more helpful guidance about study design and consultation and informed consent in disability research. 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.

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.
Informed consent

“Respect for inherent dignity, individual autonomy including the freedom to make one’s own choices, and independence of persons”

- Article 3 of the Convention

Degrees of competence:
1) Those who can give informed consent
2) Those who require assistance to give informed consent
3) Those who cannot give informed consent

“Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent”

- Right 7(2), Code of Health and Disability Services Consumers’ Rights

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 can be avoided when researchers align their conduct with the general principles laid out in Article 3 of the Convention.

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.

It should be noted that almost anyone, with the right support, is capable of providing informed consent, and the Standards reiterate that as a default position, researchers should take all people, regardless of disability, as having the capacity to provide informed consent. This is also emphasised by Right 7(2) of the Code of Rights.
5.11 A person-centred, supported decision-making model should involve:

- Providing information to participants individually and face-to-face
- Allowing adequate time
- Delivering information in a form appropriate for the individual
- Using alternative methods of communication if required
- Taking factors such as reading ability and research literacy into account
- Involving member of the individual’s support network
- In the case of children, provide assistance suitable to their status as both a child and disabled person
- Keeping a record of the consent process
- If necessary, hiring a qualified person to oversee the consent process*

*For example, the IHC provides intellectual disability support services and holds workshops on supported decision-making.

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 anyone with the right support, is capable of providing informed consent and the standards reiterate that as a default position, researchers should take all people, regardless of disability, as having the capacity to provide 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. It should be noted also that disability research is social research, and that a clinical determination of competence may not be necessary. However, all decisions should still be evidence-based and independent.

Supported decision-making depends on understanding the participant and using a carefully tailored consent process, providing for things such as reading and communication ability, research literacy, and existing dependence on support persons.
Facilitating participation

“Parties shall recognize that persons with disabilities enjoy equal capacity on an equal basis with others in all aspects of life”

- Article 12 of the Convention

5.15 Researchers should ensure that people are equally eligible to participate, regardless of their disability or any other aspect of their identity.

Justice / Mana

It is also important that Article 12 of the Convention requires that disabled people enjoy equal recognition as persons before the law, and the rights that this entails. This includes access to and representation in health research, which is a matter of justice and good research practice.

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. A fair society is one in which its members share in both the benefits and burdens of research.
Disability data

5.17 Researchers should publish the results of disability research in open-access journals. They should limit sponsor publication requirements wherever possible, and ensure that data that is of relevance to a disability issue is not concealed by a paywall.

The Marrakesh Treaty: Relevant works should be made publicly available, in an accessible format, to disabled people. Concerns around intellectual property should not limit disabled people’s access to disability data.

Beware the digital divide (the gulf between those with easy access to the internet and those without it). Availability does not mean accessibility!

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.

The analysis and dissemination of data is an important part of the research process and is how New Zealand will fulfil its Convention obligations to remove social barriers and further empower disabled people.

The principle of ‘accessibility’ is important in the data domain, and researchers should ensure at the outset that the results of their study will be readily available. This is especially important in disability research where participants are volunteering their time to help address a social problem. Making study results accessible is more than simply submitting them to an academic journal. Results should be open-access and free of sponsor or intellectual property restrictions.

Of course, data ethics brings with it considerations of harm as well. These could include harms of interpretation, to privacy, or misrepresentation. Care should be taken with terminology, which can itself be disabling. If researchers inadequately define ‘disability’ for their purposes, study results may be inaccurate or even harmful for disabled people. Disabilities do not exist in isolation, but they occur in tandem with other social problems. Additionally, researchers must take care when examining the cause of a social problem to avoid identifying a ‘disability problem’ where one does not exist.
Overall, the NEAC standards take a stronger view of inclusion, respect and show that many challenges can in fact be overcome with co-design, supported decision making and building relationships.
Informed consent

- Suitable processes for obtaining consent
- Consent as a dynamic process
- Consent must be voluntary
- Consent must be informed

Standard informed consent is a well trodden path in research ethics.

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.

Obtaining the informed and voluntary consent of participants is the default starting point in these standards.
### Modifying the consent process

- Electronic consent
- Withholding information and deception
- Integrated consent
- Abbreviated consent
- Opt-out consent
- Waiver of consent for secondary re-use of identifiable health data
- Waiver of consent for secondary use (re-use) of human tissue
- Consent for future use of health data and human tissue
- Research with adults who cannot provide informed consent

Modifying the consent process, however, was complex.

In limited circumstances, aspects of the consent process may be **modified**, or the requirement to obtain consent may be **waived**.

I will touch on some of the challenges when trying to provide flexibility when it comes to informed consent and ethics.
Challenge

- Modifying informed consent while maintaining respect for people, their mana and keeping within the law
- Can consent be simplified?
- Example: comparative effectiveness research

What are the challenges currently faced with informed consent in your research contexts?

Consent is central to the ethical conduct of research but over recent years, the traditional informed consent process for clinical trials has become long and complex. Participant information sheets and consent forms (PICFs) are widely criticised for being written in ways that obscure important detail, reduce understanding and recall and prioritise the needs of institutions to mitigate risk rather than the needs of participants.

Comparative effectiveness trials (CETs) involve interventions that are widely used in routine care. Unlike traditional trials conducted in highly controlled settings, the primary goal of CETs is to produce generalisable evidence to inform health providers and policymakers. To maximise generalisability, they are conducted in real-world settings with minimal exclusion criteria.
There is a growing consensus that traditional informed consent may poorly suit low risk CETs. Patients may also be rejecting low risk trials because of an exaggerated and disproportionate perception of risk which introduces selection bias. Furthermore, attempts to embed CETs into routine care settings are hampered because traditional consent causes levels of disruption to clinical workflows that make these trials impracticable.
Short term solution: Integrated Consent

- 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
- 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.

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.

Integrated consent processed 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 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.

What could it look like?

is no longer than 5 pages (ideally 2)

contains sufficient information for potential participants to decide whether to participate, with an additional tier of information made available for those who want it;

allows some or, in limited cases, all information to be disclosed to participants verbally (i.e. if written consent to receive the intervention(s) is not normally required outside of the research context)

is preferably consumer endorsed.
What might simplified consent look like?

- Is no longer than 5 pages (ideally 2)
- Contains sufficient information for potential participants to decide whether to participate, with an additional tier of information made available for those who want it;
- Allows some or, in limited cases, all information to be disclosed to participants verbally (i.e. If written consent to receive the intervention(s) is not normally required outside of the research context)
- Is preferably consumer endorsed.
What should a simple consent communicate?

- It is research and that participation is voluntary;
- The aims of the research - the use of data to obtain generalisable knowledge to benefit others;
- The extent to which the research will alter their care.
- The key differences for the patient between the two interventions being compared in case they have a preference on the basis of possible side effect profile etc. which would mean that randomised allocation is not desirable or appropriate.

However!

- The more research deviates from established practice, the greater the amount of information required.
- Or the more the research comparative treatments differ (i.e. in composition, SE, dosing etc)
- Or the more the comparators differ

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.
‘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.

- 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.
Most societies also have legal rules that govern behavior, but ethical norms tend to be broader and more informal than laws. Although most societies use laws to enforce widely accepted moral standards and ethical and legal rules use similar concepts, ethics and law are not the same. An action may be legal but unethical or illegal but ethical. We can also use ethical concepts and principles to criticize, evaluate, propose, or interpret laws.

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.

New Zealand law is not flexible when it comes to informed consent in research.

This requirement creates a tension when providing ethical guidance for:
research with participants who are unable to consent
opt out consent and,
cluster control trial design or general waivers of consent

At present, study designs such as cluster controlled trials are not able to be ethically approved by HDECs in New Zealand due to New Zealand law, in particular the HDC Code of Rights. The Health Research Council Ethics Committee and NEAC have written to the HDC about this potential legal barrier to ethical research, as well as other legal ethical tensions.
Health Data

- Māori data
- Data identifiability
- Benefits and harms from data use
- Privacy and confidentiality
- Storage, governance and management of data
- Directly-collected new data
- Re-use of existing data
- Determining sensitivity, level of consultation and level of data management
- Waiver of consent for secondary re-use of identifiable health data
- Data-linking
- Databanks (registries)

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. We had to address this wealth of data, and the new kinds of data linking.

Data exists in both analogue (paper) and digital (electronic) formats. Increasing digitisation means data is being collected from both ‘traditional’ sources, e.g. administrative data, electronic health records, as well as novel sources, e.g. 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 takes a broad definition towards these data sources and is
intended to encompass all of these sources and types of data which is described in these standards as ‘Health Data’. These standards should be adhered to by all researchers that hold and use data within this broader context.
Storing data often involves elements of security, governance and management, privacy, consent, and curation. Data can be used in a variety of fashions: 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).

Importantly, consent and identifiability are becoming less effective as a means of respecting peoples data, and the storage and management of that data is becoming increasingly important. Our standards recognise the complex ethical balance required for using data and respecting people, and aim to provide guidance for ethical use.
What are the biggest challenges you experience when it comes to study data?
- examples: journals requiring more data, raw data, re-use of data later on,
### Identifiable data

Data from which it can reasonably be assumed that it is possible to identify a specific individual involved in the study

#### Direct identifiers
- NHI
- Name
- Street address
- Phone number
- Online identity (e.g., email, twitter name)
- Identification numbers (e.g., community services card, driver’s licence).

#### Indirect identifiers
- 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.

De-identified data
- 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:
  - 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

Anonymised data
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.

A minimal operational standard of anonymity should:
- 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:
  - 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.
Determining sensitivity, level of consultation and level of data management

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.

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 reuse, and the appropriate level of data management (Hudson et al. 2017).

<table>
<thead>
<tr>
<th>Concept</th>
<th>Level of Sensitivity</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tapu</td>
<td>Level of sensitivity</td>
<td>How sensitive is the data?</td>
</tr>
<tr>
<td>Noa</td>
<td>Level of accessibility</td>
<td>How accessible should this data be?</td>
</tr>
<tr>
<td>Tika</td>
<td>Level of value</td>
<td>How does the use of this data add value to the community?</td>
</tr>
<tr>
<td>Pono</td>
<td>Level of trust</td>
<td>Will the community support this use of the data?</td>
</tr>
<tr>
<td>Mauri</td>
<td>Level of originality</td>
<td>How unique is the data?</td>
</tr>
<tr>
<td>Wairua</td>
<td>Nature of the application</td>
<td>Is the data being used in the same spirit as its original use?</td>
</tr>
<tr>
<td>Whakapapa</td>
<td>Level of relationship</td>
<td>Does the user have an existing relationship with the data?</td>
</tr>
<tr>
<td>Pukenga</td>
<td>Level of expertise</td>
<td>Does the user have the expertise and experience to use data in a culturally appropriate manner?</td>
</tr>
<tr>
<td>Kaitiaki</td>
<td>Level of authority</td>
<td>Will the data be protected from inappropriate use?</td>
</tr>
<tr>
<td>Wānanga</td>
<td>Level of responsibility</td>
<td>Does the institution have the necessary infrastructure to ensure the use of the data in a culturally appropriate and ethical manner?</td>
</tr>
</tbody>
</table>

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.

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.
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.
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).

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.

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.
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 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.
Increased the focus on storage, governance and management of data

- 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

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.
New requirements for waiver of consent for secondary re-use of identifiable health data / tissue

- 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:
  - There are scientific, practical, or ethical reasons why consent cannot be obtained.
  - Appropriate data governance plans are in place.
  - 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.
  - 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.
    - 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.
Public consultation also raised the need to address emerging technologies. NEAC and the Ministry tasked an expert working group to produce content on the application of artificial intelligence to health data. A chapter was developed which acknowledged the evolving nature of these technologies, and which identified the salient ethical issues and contained broad guidance on the use of artificial intelligence.

This chapter, and the health data content more generally, was subject to targeted consultation with experts in the field, including representatives from Statistics New Zealand, before being finalised through discussion between NEAC and the working group.

Health products powered by artificial intelligence, or AI, are streaming into our lives, from virtual doctor apps to wearable sensors and drugstore chatbots.

IBM boasted that its AI could “outthink cancer.” Others say computer systems that read X-rays will make radiologists obsolete.
“There’s nothing that I’ve seen in my 30-plus years studying medicine that could be as impactful and transformative” as AI, said Eric Topol, a cardiologist and executive vice president of Scripps Research in La Jolla, Calif. AI can help doctors interpret MRIs of the heart, CT scans of the head and photographs of the back of the eye, and could potentially take over many mundane medical chores, freeing doctors to spend more time talking to patients, Topol said.

And although software developers may boast about the accuracy of their AI devices, experts note that AI models are mostly tested on computers, not in hospitals or other medical facilities. Using unproven software “may make patients into unwitting guinea pigs,” said Ron Li, medical informatics director for AI clinical integration at Stanford Health Care.

AI systems that learn to recognize patterns in data are often described as “black boxes” because even their developers don’t know how they have reached their conclusions. Given that AI is so new—and many of its risks unknown—the field needs careful oversight, said Pilar Ossorio, a professor of law and bioethics at the University of Wisconsin-Madison.
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 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.

Doctors at New York’s Mount Sinai Hospital hoped AI could help them use chest X-rays to predict which patients were at high risk of pneumonia. Although the system made accurate predictions from X-rays shot at Mount Sinai, the technology flopped when tested on images taken at other hospitals. Eventually, researchers realized the computer had merely learned to tell the difference between that hospital’s portable chest X-rays—taken at a patient’s bedside—with those taken in the radiology department. Doctors tend to use portable chest X-rays for patients too sick to leave their room, so it’s not surprising that these patients had a greater risk of lung infection.

A KHN investigation published in March found sometimes life-threatening errors in patients’ medication lists, lab tests and allergies.

In view of the risks involved, doctors need to step in to protect their patients’ interests, said Vikas Saini, a cardiologist and president of the nonprofit Lown Institute, which advocates for wider access to health care.

“While it is the job of entrepreneurs to think big and take risks,” Saini said, “it is the job of doctors to protect their patients.”
We have moved away from thinking of groups as vulnerable. Instead, we look at the sources of vulnerability and how to manage it.

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.

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.
Research benefits and harms
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.

Research can generate benefits for individuals now and in the future, yet all research carries some risk of harm. The vicarious nature of research, where some individuals accept these risks not only for themselves but for the greater public good, presents an ethical problem which must be managed. There must be a balance between research benefits and harms at both the individual and societal level.

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.

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. The level of risk that is acceptable is up to the potential participants to determine.
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.
COMMUNITIES

- 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
- 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)
<table>
<thead>
<tr>
<th>Society</th>
<th>Researchers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Knowledge advancement (e.g. Through research outputs, hui and wānanga)</td>
<td>• Status and reputation, mana</td>
</tr>
<tr>
<td>• Inclusiveness and diversity within the research system</td>
<td>• Qualifications (e.g. Through research conducted for masters and phd theses)</td>
</tr>
<tr>
<td></td>
<td>• Personal advancement, particularly enhanced publication records</td>
</tr>
<tr>
<td></td>
<td>• Increasing networks</td>
</tr>
<tr>
<td></td>
<td>• Broadened life experiences and skills</td>
</tr>
<tr>
<td>Category</td>
<td>Potential harms</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Physical harm</td>
<td>Injury, illness, pain, permanent disability, death</td>
</tr>
<tr>
<td>Psychological harm</td>
<td>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)</td>
</tr>
<tr>
<td>Disrespect or harm to dignity</td>
<td>Devaluation of personal worth, including being humiliated, manipulated or in other ways treated disrespectfully or unjustly</td>
</tr>
<tr>
<td>Social or cultural harm</td>
<td>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</td>
</tr>
<tr>
<td>Privacy harm</td>
<td>Identification or disclosure of private information</td>
</tr>
<tr>
<td>Economic harm</td>
<td>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.</td>
</tr>
<tr>
<td>Legal harm</td>
<td>Discovery of criminal conduct or prosecution for it</td>
</tr>
<tr>
<td>Data harm</td>
<td>Surveillance, inferential harm or social harm such as stigmatisation</td>
</tr>
<tr>
<td>Autonomy harm</td>
<td>Coercion, inducement, undue influence, loss of agency</td>
</tr>
</tbody>
</table>

Researchers must equally gauge the potential harms of their research which the aforementioned benefits must off-set. Some additional considerations include the risks of harms to those other than research participants, such as potential stigma and whakamā to communities or groups. Potential harm to research personnel should also be minimised, such as distress when working with sensitive subject matter.

These having been considered, the risk of harm to research participants directly needs to be clearly identified and mitigated. The risk of physical injury is an obvious harm to be accounted for, such as adverse reactions to study drugs in clinical trials. Some more abstract yet equally important potential harms range from reactions to the conduct of the study – for instance, a participant may be psychologically, culturally, or autonomously harmed if a researcher disregards a request for whānau consultation without cause – to the means through which results are disseminated – for example, a PhD student conducting research on a disadvantaged population should make their dissertation public, both to make potentially beneficial knowledge available and as a mark of respect and appreciation of that community.
Categorising risk

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negligible</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Research in which the risk for participants is more serious than discomfort is not low risk (NHMRC 2018).</td>
</tr>
<tr>
<td></td>
<td>Discomfort includes such things as minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

The Standards adopt four levels of risk stratification which take into account the types of potential harms individuals will be exposed to, and which are used to determine 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.

Research is negligible risk when the only foreseeable risk is one of inconvenience and/or discomfort. Discomfort includes such things as minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview. Discomfort should however 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 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).
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.

Examples of research aspects which categorically constitute more than minimal risk include withholding standard care and using tissue samples for a secondary purpose without the donor’s specific consent.

Some of these activities will incur further risk depending on the context and specifics of the project. 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.
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).
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.

8.16 Researchers should ensure:

- 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
- groups that are unlikely to benefit from any knowledge gained from the research do not bear a disproportionate share of risks
- 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.
Research development and design

We are recognising the role of consumers and patients

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.

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. Health research helps to track the growing diversity of the
population, and to provide more detailed information for planning, funding and monitoring health services.
Ethical features of studies

- Observational studies
- Examples of observational research
- Qualitative research
- Intervention studies
- Managing risks of harm in intervention studies
- Incremental testing in early-phase trials
- Access to an intervention after the study
- Equipoise
- Controls
- Cross-over studies and wash-out periods
- Equivalence or non-inferiority trials
- Adaptive design trials
- Cluster randomised trials
- Epidemiological and public health research studies
**Research conduct**

- Overall responsibility for a study
- Clinical trial registration
- Whakapapa
- Identifying potential participants
- Recruitment methods
- Approaching potential participants
- Advertising
- Social media
- Reimbursements, koha and incentives for participants
- Managing conflicts of interests or role conflict
- Safety and Data Monitoring

- Coordinating centres or database monitoring
- Responsibilities for adverse event monitoring
- Terminating a study
- New information
- Disclosing information
- Returning results and incidental findings
- Communicating and disseminating research results
- Interpreting and presenting study results
- Timing the release of results
- Releasing all results
- Charging participants
- Maintaining the safety of researchers

I won’t go into detail on this chapter, but as you can see we cover a broad range of important topics:

- Overall responsibility for a study
- Clinical trial registration
- Whakapapa
- Identifying potential participants
- Recruitment methods
- Approaching potential participants
- Advertising
- Social media
- Reimbursements, koha and incentives for participants
- Managing conflicts of interests or role conflict
- Safety and Data Monitoring
- Coordinating centres or database monitoring
- Responsibilities for adverse event monitoring
- Terminating a study
- New information
- Disclosing information
• Returning results and incidental findings
• Communicating and disseminating research results
• Interpreting and presenting study results
• Timing the release of results
• Releasing all results
• Charging participants
• Maintaining the safety of researchers
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.
Quality Improvement

- General Ethical considerations in QI
  - Changes in standard of care
  - Informed consent and quality improvement
- Types of quality improvement activities
- Accountability for the ethical conduct of quality improvement

The bullet points in slides are the sub-headings for the Standards, under which we provide Standards and commentary in the document.

Public consultation informed us that QI presented a significant gap in the first draft of the document. We chose to address this in our research ethics standards because increasingly the distinction is less important, and QI share many features of research.

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 assume 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.

Compared with research, quality improvement activities typically have more predictable benefits and reduced risks. They are generally specifically
directed at improving the delivery of services or providing benefits to the public by addressing risks to public health. For this reason, it is unethical for quality improvement activities not to investigate health care or disability services or a public health risk.

All the same, 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.
We have new ethical guidance on health system improvement research.

The health sector has a critical role in conducting health services research and in translating research findings into policy and practice. 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. See https://www.health.govt.nz/publication/new-zealand-health-research-strategy-2017-2027 for more information on New Zealand’s Health Research Strategy.
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 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. In fact, over time the distinction may become less relevant, as we move towards integration of research into routine care.

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).
While the standards 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.
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.
But we didn’t leave it at that, NEAC have worked with a range of researchers, DHBs and QI practitioners to develop guidance to help researchers and health service providers determine what their activity is, via the following table:
### Human participant research vs. Quality improvement activities

<table>
<thead>
<tr>
<th>Description</th>
<th>Goal</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Activities which attempt to create new generalisable knowledge in response to an acknowledged information gap.</td>
<td>- Activities which aim to improve healthcare by assessing current situation and systematically implementing/testing evidence-based knowledge within a local organisation.</td>
<td>- May be conducted within a health and care or community setting.</td>
</tr>
</tbody>
</table>

### Goal
- **Quantitative research**
  - 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.
  - Ensure healthcare delivered by organisations are effective, safe, and equitable through the applications of improvement science methodology.

- **Qualitative research**
  - Description and interpretation of something in its natural setting. May address how treatments and relationships are experienced.

This table helps identify features of activities to determine whether a project is or is not research. NEAC acknowledges that the line between the two activities is often grey.

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.

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 (i.e., clinical audit or service improvement) or a secondary purpose (i.e., 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 ensure the activity has been conducted in accordance with these Standards and should inform the editor concerned whether ethics committee review is required.
## Human participant research

### Methods

**Quantitative research**
- 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.

**Qualitative research**
- Obtains information from interviews, focus groups, observations, or documents or other materials
- Uses established, structured quality improvement methodologies to evaluate baseline performance, implement change and retest for sustained improvement.
- Approach’s 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.
- 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.
Human tissue was not covered at all in the 2012 guidelines. We addressed that in full. 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.
Similarly, biobanking has been addressed in full, addressing major gaps in ethical guidance in New Zealand.

Again, we are incredibly fortunate to have researchers and academics in New Zealand who have provided extensive guidance on biobanking and Maori, where we can integrate Maori concepts and values into our ethical guidance. 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
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.
Thank you
Questions