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Cross-sectoral ethics arrangements for health and disability research

Discussion document

National Ethics Advisory Committee

Kāhui Matatika o te Motu

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# ****Introduction and purpose****

The National Ethics Advisory Committee (NEAC) is seeking your views on existing cross-sectoral ethics arrangements for health and disability research.

Health and disability research ethics arrangements include:

* responsibility for the ethical design, review, conduct and monitoring of health and disability research; and
* the standards, processes and structures to support and facilitate this responsibility.

This discussion document summarises NEAC’s analysis of the:

* current ethics arrangements
* issues with these arrangements
* current responses to issues
* other possible responses to issues.

Your feedback will help to inform advice to the Associate Minister of Health on current issues and how these may be addressed. Your feedback will also inform NEAC’s review of *Ethical Guidelines for Observational Studies* (2012) and *Ethical Guidelines for Intervention Studies* (2012).

# How to have your say

We are seeking feedback by **27 February 2015**.

To take part, please complete the submission form, which you can access on NEAC’s website <http://neac.health.govt.nz/consultations>. You can complete the submission form electronically and send by email to neac@moh.govt.nz or post a printed copy to us:

National Ethics Advisory Committee Secretariat

PO Box 5013

Wellington 6145

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

Your feedback will be analysed and summarised by secretariat staff. The analysis of submissions will be considered by NEAC and assist the committee to provide advice to the Associate Minister of Health.

# Definitions

## What is health and disability research?

Health and disability research is research that aims to generate knowledge for the purpose of improving health and independence outcomes. There are two main types of health and disability research.

* Observational studies: the researcher has no control over study variables and observes outcomes through recording, classifying, counting and analysing data eg, cohort studies, audits.
* Intervention studies: the researcher controls the interventions provided to participants and studies the outcomes of the intervention(s) for the purpose of adding to knowledge of the health effects of the intervention(s) eg, randomised control trials.

## What is research ethics?

Health and disability research ethics is primarily concerned with:

* facilitating conduct of high quality studies that add to knowledge of matters relating to health and/or disability
* ensuring that all participants in research are aware of what their participation will involve and have given informed consent
* preventing studies that pose an unacceptable risk of harm to participants from going ahead.

## What are health and disability research ethics arrangements?

Health and disability research ethics arrangements include:

* responsibility for the ethical design, review, conduct and monitoring of health and disability research; and
* the standards, processes and structures to support and facilitate this responsibility.

## Responsibility for ethical design, review, conduct and monitoring

It is widely accepted that the researcher has the primary responsibility for good design and conduct of research, including ensuring that it accords with applicable ethical principles and standards. Researchers are also responsible for communicating results in a timely, understandable and appropriate way. These responsibilities are shared with others including the host organisation, sponsors, ethics advisory and standard setting bodies, and ethics review committees.

Similarly, the researcher and sponsor of the research have primary responsibility for proactively monitoring the research. Ethics review committees play a limited role through reporting processes.

## Standards, processes and structures

New Zealand’s ethics system includes the standards, processes and structures to support and facilitate this shared responsibility for good design and conduct of research. These include:

* ethics advisory and standard setting bodies
* ethics review committees
* research funding processes
* legislation, regulations and codes
* health and disability research guidance
* codes of ethics.

All researchers have a duty to comply with NEAC’s established ethical standards *Ethical Guidelines for Observational Studies* and *Ethical Guidelines for Intervention* *Studies* when conducting health and disability research in New Zealand. This is an explicit duty for all researchers submitting proposals for Health and Disability Ethics Committee (HDEC) review.

## New Zealand’s cross-sectoral research ethics arrangements

New Zealand has a complex health and disability research ethics environment involving a range of organisations and stakeholders (see Figure 1). There are many parties involved including researchers, ethics committees, research funding and host organisations, and research sponsors. An array of standards, processes and structures support and facilitate the roles and responsibilities of these parties.

Figure 1: An overview of New Zealand’s cross-sectoral research ethics landscape

**Bodies that undertake peer review/assess scientific validity**

* HRCEC
* Universities
* Localities (organisations responsible for site of research)
* SCOTT
* GTAC

**Ethics review bodies**

* HDECs
* IECs
* HRCEC
* ECART

**Ethics advisory bodies**

* HRC
* NEAC
* ACART
* Royal colleges
* HDC
* Ministry of Health
* Health regulatory bodies

**Other Ethics Committees**

* Plunket
* ACC
* New Zealand Ethics Committee

**Key:**

ACART Advisory Committee on Assisted Reproductive Technology HDC Health and Disability Commissioner

ACC Accident Compensation Corporation HDEC Health and Disability Ethics Committee

CRI Crown Research Institute HRC Health Research Council

CRO Contract Research Organisation HRCEC Health Research Council Ethics Committee

DMCC Data Monitoring Core Committee IEC Institutional ethics committee

ECART Ethics Committee on Assisted Reproductive Technology NEAC National Ethics Advisory Committee

GTAC Gene Technology Advisory Committee SCOTT Standing Committee on Therapeutic Trials

**Bodies managing or organising research**

* Sponsors
* CRIs
* CROs
* DHBs and Universities
* Government agencies

**Complaint bodies**

* HDC
* Health regulatory bodies
* Employers
* Locality
* Privacy Commissioner

**Accreditation**

HRCEC

**Monitoring bodies**

* DMCC
* HDECs
* Sponsors and CROs

**Funders**

* HRC
* Universities
* Government agencies eg, Ministry of Health
* Sponsors
* Localities
* Other institutions

Researchers

Participants

.

# Background

## About NEAC

NEAC is an independent advisor to the Minister of Health. NEAC was established in 2001 by section 16 of the New Zealand Public Health and Disability Act 2000. Its statutory functions include advising the Minister on ethical issues for health and disability matters and determining nationally consistent ethical standards across the health sector.

## Background to this review

### NEAC’s advice on Health Select Committee clinical trials inquiry

In 2010, the Health Select Committee (Health Committee) opened an inquiry into improving New Zealand’s environment to support innovation through clinical trials. NEAC advised the Minister of Health on issues being considered by the Health Committee in its inquiry. As part of this advice, NEAC recommended a review of the cross-sectoral ethics arrangements, stating that, overall, there is significant potential for the many sources of ethics committee standards and accountabilities to produce overlaps, inconsistencies, and related practical issues.

NEAC is aware that the research community continues to express concern about the absence of a comprehensive framework for all research bodies. This is considered particularly important given the changes to HDECs in 2012. These changes included new standard operating procedures (SOPs) to better define the HDEC review process, an online application process, changes to the scope of what HDECs review and a reduction in the number and size of HDECs.

### Development of this document

As the first step in this review, NEAC undertook an environmental scan of the research ethics landscape in New Zealand. The roles and functions of the various ethics committees and ethics advisory and standard setting bodies are summarised in Appendix 1. NEAC also reviewed ethics arrangements in Australia and the United Kingdom and, where helpful, international practices are discussed in this document.

In 2013, NEAC met with a limited range of stakeholders to inform its work (see Appendix 2). These meetings sought to identify the ongoing issues for ethical review and gather views on how to address these issues, including who has a role, or would be appropriately placed, to resolve these issues. NEAC recognises that there are likely to be other issues that were not identified through this process and looks forward to hearing about these through the consultation process.

# Scope of this review

This discussion document focuses on:

* health and disability research – it does not discuss other health and disability services or research that is not health or disability-related
* governance arrangements for health and disability research ethics – it does not discuss governance arrangements for other aspects of health and disability research.

# Issues for discussion

This section outlines issues associated with six aspects of the cross-sectoral research ethics arrangements.

1. Complex research ethics landscape
2. Māori and health research
3. Alternative ethical review structures
4. Peer review for scientific validity
5. Audit and audit-related activity
6. Innovative practice

Under each section there is a discussion of the current ethics arrangements, issues with these arrangements, current and other possible responses, and questions for feedback.

## Complex research ethics landscape

### 1.1 Current ethics arrangements

### Overall responsibility

There is no single body in New Zealand with overall responsibility for the ethical review process for health and disability research. The ethical review process is characterised by a complex set of relationships and responsibilities across a range of organisations.

### Ethical approval process

New Zealand has a mix of publicly funded ethics review committees established under statute (eg, HDECs) and ‘institutional’ ethics committees established by universities, private industry and other research organisations. This means that the ethics review system is significantly cross-sectoral, spanning health and tertiary education as well as public and private sectors. Ethical review processes may also vary across institutional ethics committees. For example, students undertaking low risk research at Massey University register with a low risk database, which is audited but not formally assessed by the Massey Ethics Committee. At Otago University, low risk research is approved by the Head of Department, and these applications are later reviewed by the Otago Ethics Committee.

### Guidelines and standards

Standards and guidelines for New Zealand’s ethics approval system are set mainly by health sector organisations including the Ministry of Health, NEAC and the Health Research Council (HRC). Additional standards are set for each institutional ethics committee by the parent organisation.

There are a range of guidelines and standards that researchers need to be aware of when planning and undertaking research including legislation, international statements, codes of conduct and ethical guidelines (see Appendix 3 for further detail).

### 1.2 Issues

### Applying guidelines and standards

Researchers have suggested that the lack of a clear framework or ‘one-stop-shop’ for the various guidelines and standards for ethical review is a barrier to navigating the ethics landscape. Identifying relevant documents and piecing them together is not an easy exercise, even for the more experienced researcher.

It can also be difficult to determine what ethical review process should be followed for a specific research project. The *Standard Operating Procedures* for HDECs includes a flow diagram to help researchers step through the criteria, exemptions and inclusions for HDEC review. However researchers are still required to use their judgement in deciding whether the research meets the threshold for review, for example, the level of risk and the potential for identifying individuals.

### Accessing ethical review

If a research project does not meet the criteria for HDEC review then it may still benefit from ethical review from an alternative review body if there are unresolved ethical issues or in order to meet requirements for funding or publication.

Where a research application is precluded from HDEC review, the onus is on the researcher to seek alternative ethical review or ensure proper processes have been followed. Some researchers may be able to access an ethics committee within or associated with their organisation. For other researchers there may be few, if any, alternative options. This is the case for researchers in some government departments and community organisations.

### Monitoring and accountability

Researchers are responsible for good design and conduct of research, including complying with all relevant legal requirements and adhering to the agreed and ethically approved study. Researchers are also responsible for communicating results (including positive, negative, significant and non-significant results) in a timely, understandable and appropriate way so that the widest possible community stands to benefit. However, it is not entirely clear who is responsible for ensuring researchers fulfil these obligations.

There is no agreed accountability framework for ethics committees and NEAC is not aware of any consistent approach for monitoring the performance of ethics committees. For example, neither the standard operating proceduresnor the terms of reference for each HDEC indicate who, if anyone, is responsible for ensuring that HDECs meet their responsibility to act lawfully, or to consistently apply the ethical standards set by NEAC to each application they review.

### 1.3 Current responses

### Applying guidelines and standards

In 2003, NEAC published its statement of *Goals, objectives and desired outcomes of an ethical review system*[[1]](#footnote-1)(see Appendix 4). The statement was updated in 2010. The goals cover four areas: contributing to knowledge and improved health outcomes; protecting participants; balancing risks and benefits; and recognising and respecting the principles of the Treaty of Waitangi. Desired outcomes are specified for six objectives: accountable, enabling, informed, enabling of Māori participation, fair and efficient.

Some researchers are able to access support from within their organisation or from researcher networks to help decide which guidelines and standards are relevant to their research. However, this level of collegial support is not consistently available.

Relevant resources for ethical review are available through the HRC’s website[[2]](#footnote-2) and NEAC’s guidelines set out the range of guidelines and standards that researchers need to be aware of when planning and undertaking research.

### Accessing ethical review

A number of alternative ethical review structures have been set up in District Health Boards (DHBs) and institutions to undertake ethical review of research that does not meet HDEC criteria. Other researchers that have studies excluded from HDEC review have made arrangements with institutional ethics committees to access ethical review of their studies but this is ad-hoc and usually dependent on individual relationships. NEAC has also received anecdotal evidence of researchers answering HDEC screening questions in such a way to ensure they can access HDEC review.

### Monitoring and accountability

Health professionals undertaking research are required to follow the codes of practice issued by their respective health regulatory body, as well as the Code of Health and Disability Services Consumers’ Rights. Some of the regulatory authorities play a disciplinary role, dealing with complaints about, and taking action in relation to, a breach of professional ethical standards, including those related to research. This disciplinary role is also shared with the Health and Disability Commissioner. However, there are no publicly available cases that relate to misconduct in research.

Requirements for researchers to adhere to the approved study protocol, to act lawfully and to publish results are also apparent in formal arrangements, such as in contractual and employment agreements with institutions and sponsors, and informally, through colleagues and research networks.

HDECs report annually to the Minister of Health. The Ministry of Health is currently working to improve processes and monitor HDECs, including the quality of HDEC review. This work may include using case studies or dummy applications to measure the quality of HDEC decision-making, for example, looking at whether their decisions are consistent, or understanding why different decisions may be made by different HDECs. This approach is similar to the UK’s Health Research Agency’s quality assurance programme, which requires National Health Service ethics committees to review a single application. The review helps committees to improve consistency in decision-making, to encourage an ethical debate across committees and to review the current guidance related to the application.

### 1.4 Other possible responses

### Applying guidelines and standards

It is unclear how useful NEAC’s statement of *Goals, objectives and desired outcomes of an ethical review system* is as a strategic framework for the ethical review system. There may be scope to further develop and/or promote this tool within the research community.

An enhanced framework might help researchers understand their responsibilities and how the various standards, processes and structures fit together in the New Zealand context. The framework could usefully be adapted into an interactive website or an online step-by-step guide for researchers to help them make appropriate decisions about ethical review for their research.

This is the approach taken by the UK’s National Research Authority[[3]](#footnote-3), which provides a ‘one-stop-shop’ of guidance to the research community. The National Research Authority’s website is arranged as a journey through the research process, with detailed information and guidance at each stage, including for ethical review. It also covers research not undertaken in the NHS, such as social care research, and directs the reader to other relevant bodies.

### Accessing ethical review

The research community has made a number of suggestions for accessing ethical review when a study does not meet the criteria for HDEC review. These include:

* providing the option of informal ethical review/advice to researchers whose study is classified as minimal risk research (and therefore excluded from HDEC review)
* allowing researchers to opt in for ethical review by an HDEC if they consider their research requires ethical review and there is no other alternative
* establishing new ethical review structures for specific types of research where specialist knowledge is important, for example, innovative practice and trials of medical devices.

In the UK, research ethics committees in the NHS can be ‘flagged’ as having expertise in reviewing particular types of research, for example, research involving prisoners, or those involving participants that lack the capacity to consent. Some ethics committees have mandatory flagging for certain types of research, such as for a medical device study or qualitative research.

### Monitoring and accountability

It is unclear how current monitoring and accountability issues could best be addressed and NEAC invites feedback on this issue.

### 1.5 Questions

1. What could be done to achieve more cohesion across the ethical review system?
2. How useful is NEAC’s statement of *Goals, objectives and desired outcomes of an ethical review system (GODO)*?
3. Are the GODO goals adequately covered by the objectives?
4. How could the GODO statement be improved?
5. Is the plurality of functions that various public agencies (eg, Ministry of

Health, NEAC, HRC) have to set standards for researchers and for ethics committees sufficiently clear and coherent overall?

1. What would help parties involved in research navigate through the current system?
2. What mechanism(s) could be used to direct or facilitate access to ethical review where a researcher is otherwise unable to access it?
3. What would an opt-in review option for HDECs mean for HDEC workloads, and how would it fit with the recent changes? Does this have the potential to create inefficiencies?
4. Who could provide informal advice for borderline cases for HDEC review or minimal risk applications excluded from HDEC review?
5. How might monitoring and accountability mechanisms for researchers (eg, to ensure good design and conduct of research and communication of results) be improved?
6. How might monitoring and accountability mechanisms for ethics committees be improved?

## Māori and health research

### 2.1 Current ethics arrangements

All health research conducted within New Zealand is of relevance to Māori. As a Treaty partner and a priority population requiring appropriate health intervention, Māori involvement in health research is critical.[[4]](#footnote-4) The principles of partnership, participation and protection implicit in the Treaty should be respected by all researchers, and, where applicable, should be incorporated into all health research proposals.[[5]](#footnote-5)

NEAC’s *Ethical Guidelines for Observational Studies* and *Ethical Guidelines for Intervention Studies* explain the three Treaty principles:

* partnership: working together with iwi, hapū, whānau and Māori communities to ensure Māori individual and collective rights are respected and protected in order to achieve health gain
* participation: involving Māori in the design, governance, management, implementation and analysis of research, particularly research involving Māori
* protection: actively protecting Māori individual and collective rights, and Māori data, cultural concepts, norms, practices and language in the research process.

The HDEC *Standard Operating Procedures* make it clear that researchers are responsible for ensuring that Māori are consulted in the development, and conduct, of studies. Where formal consultation with Māori is required by HRC’s *Guidelines for Researchers on Health Research Involving Māori*, HDECs should check that the consultation has been or will be carried out appropriately. Localities are responsible for checking that studies appropriately address local cultural issues (including any formal consultation with Māori).

### 2.2 Issues

Several stakeholders have suggested that much more needs to be done to ensure that Māori interests and issues have an impact on the way research is designed, conducted, analysed and disseminated. Concerns have been raised about the adequacy of Māori consultation undertaken by researchers and the ability of researchers to identify benefits for Māori and manage cultural issues. When consultation is required, it needs to be done at a much higher level than is currently the case.

Specific research areas raise particular concerns for Māori. Where research involves the body and its parts, concerns have been expressed for Māori in relation to the nature of consent for such research, consent for future and undisclosed or unknown use, ongoing storage in tissue banks and the establishment of cell lines.[[6]](#footnote-6)

Genetic research is an area of prime sensitivity because of its association with whakapapa.[[7]](#footnote-7) The association of genetic susceptibility to disease with ethnicity is problematic for population genetic research, with the potential for community disruption, stigmatisation, stereotyping or undermining either through research processes or outcomes. Māori communities are also concerned about new technologies and research in areas such as genetic engineering, the creation of transgenic life-forms, and human genome research investigating human variation and diversity in indigenous populations.[[8]](#footnote-8)

Suggested ways to address these concerns include improving guidance, increasing availability of advice and increasing expertise on ethics committees (at least one HDEC member should have a recognised awareness of te reo Māori and understanding of tikanga[[9]](#footnote-9) Māori).

Smith (2014)[[10]](#footnote-10) argues for an inclusive approach where Māori ethical ideas and frameworks are at the centre of ethical codes and guidelines. Cultural constructs would impact the whole research exercise and not be seen merely as ‘add-ons’. Such an approach would ensure that Māori issues and interests are at the centre of ethical conversations and result in research outcomes that are genuinely relevant to Māori interests, aspirations and wellbeing. Getting the ethics right for Māori could also mean, as some commentators have stated, that we will get it right for everyone.

### 2.3 Current responses

Currently, guidance on Māori ethical ideas and frameworks are largely contained in separate documents rather than being integrated in the general research guidelines.

The HRC’s *Guidelines for Researchers on Health Research Involving Māori* inform researchers about consultation and the processes involved in initiating consultation with Māori. These guidelines note that the extent of any consultation should always be appropriate to the scale of the intended project, its relevance and significance to Māori health and the potential for application of the research results. These guidelines also discuss processes for research that breaches tikanga or involves culturally sensitive issues and genetic research involving Māori participants.

*Te Ara Tika. Guidelines for Māori Research Ethics: A framework for researchers and ethics committee members* is included as an Appendix to the *Guidelines for Researchers on Health Research Involving Māori*. *Te Ara Tika* outlines a framework for addressing Māori ethical issues within the context of decision-making by ethics committee members. The framework identifies four tikanga based principles: whakapapa (relationships), tika (research design), manaakitanga (cultural and social responsibility) and mana (justice and equity). Three levels of expectations (minimum standards, good practice and best practice) are described for each principle.

There are many other resources that provide guidance for research with Māori, such as the Rangahau website ([www.rangahau.co.nz](http://www.rangahau.co.nz)) and the website dedicated to kaupapa Māori research (www.kaupapamaori.com). Other documents provide guidance on specific issues. For example, NEAC’s *Ethical Guidelines for Observational Studies* provides guidance on collective consent.

All District Health Boards have Māori managers and iwi partnership boards that are able to provide advice and support to researchers.

The University of Otago’s *Research Consultation with Māori Policy* provides a framework for an appropriate and mandated consultation process with Māori for research. The Kaitakawaenga Rangahau Māori (Facilitator Research Māori) facilitates access to relevant information on consultation and operates as an intermediary between the University and Ngāi Tahu. The Ngāi Tahu Research Consultation Committee advises on areas that are likely (and unlikely) to be of interest to Māori and arranges detailed consultation if required.

Researchers who are not affiliated with a DHB or university are able to access Māori advisory services through Waitematā and Auckland DHBs.[[11]](#footnote-11) The fee for review is $500 and the turnaround time is 28 days.

### 2.4 Questions

1. What additional support or guidance on Māori research ethics would be helpful?
2. How could Māori ethical ideas and frameworks be placed at the centre of research guidelines?
3. Would integrating Māori ethical ideas and frameworks into the core principles of New Zealand’s general research guidelines be one way of contributing to or supporting placing Māori ethical ideas and frameworks at the centre of research guidelines?
4. What are the barriers for researchers in undertaking an appropriate consultation process with Māori?
5. What mechanisms could be available for HDECs to obtain further advice, if required, on Māori consultation and research design?
6. What more could be done to ensure research outcomes are relevant to Māori interests, aspirations and wellbeing?

## Alternative ethical review structures

### 3.1 Current ethics arrangements

As a result of the reduction in scope for HDEC review, new ethical review structures have been developed, or existing ethical review structures strengthened to provide another avenue for research that does not require HDEC review. These alternative ethical review structures have emerged as a sector-driven response to ensure access to quality ethical review.

Examples of newly formed alternative ethical review structures include:

* Otago University Human Ethics Committee (Health) - established in response to an increasing number of health research applications being submitted to the university’s existing ethics committee that had a lack of expertise to deal with these applications.
* New Zealand Ethics Committee - established through a one-off grant from the Ministry of Social Development to serve any researcher not eligible for ethics review from institutional ethics committees or HDECs. In 2013, the New Zealand Ethics Committee received 14 applications.

An approach to assuring effective governance is the HRC Ethics Committee (HRCEC) approval of ethics committees that carry out independent ethical assessment of proposed research submitted for an HRC grant. Four HDECs and nine institutional ethics committees are currently HRCEC approved. HRCEC guidelines set out the requirements for approval including membership, policies and procedures, responsiveness to Māori and ethical standards and approved committees are required to report annually and standards must be maintained for continuity of approval.

### 3.2 Issues

The research community has expressed concern about the varying status of different ethical review structures, an absence of a consistent governance policy for new structures, and uncertainty about whether parent institutions are covered by existing indemnity arrangements.

The unaccredited nature of some structures could bring into question the quality of review. The key considerations for gaining HRCEC approval are that the ethics committee is able to offer sufficient protection to the research participants and can maintain the reputation of ethical review. Where an ethics committee has not received HRCEC approval or other external review, there may be less confidence in the functioning of the committee. For example, there may be concerns about whether the membership reflects the knowledge and expertise required for quality ethical review or whether the committee is meeting internationally set standards.

It has also been suggested that being unaccredited impacts on the ability of an ethics committee to secure ongoing funding, even though there is evidence of demand for review from researchers. A further issue, that remains untested, is whether an unaccredited alternative structure is covered by the relevant institution’s indemnity arrangements. NEAC would be interested in receiving any information that would help to clarify this.

Researchers who have sought approval from unaccredited ethics committees may find that this approval is considered inadequate when trying to publish their research findings.

### 3.3 Current responses

### The HRCEC recognises that ethics committees may seek approval even if they do not review HRC funded research or if only some research they review is HRC funded. However, the HRCEC has reported that this rarely happens.

Some ethical review committees have good processes for seeking expert opinion when it is clear that the committee does not have that expertise. For example, the Auckland University of Technology Ethics Committee will refer to the HRC or seek relevant expert advice for particular applications and the Otago University Human Ethics Committee (Health) will seek advice from external experts where required.

The New Zealand Ethics Committee’s indemnity status is clearly outlined in the application form for researchers seeking ethical review. An indemnity clause states that the Committee does not assume responsibility for any legal liability that might be incurred by a researcher in carrying out research that it has reviewed. Researchers are required to sign a statement that they agree to indemnify the New Zealand Ethics Committee against any action by a third party as a result of the research.

### 3.4 Other possible responses

### Accreditation and monitoring

In general, ethics committees that do not have HRCEC approval are reviewing low risk research. A formal approval process such as that offered by the HRCEC may not be necessary for these committees. It may be more appropriate to develop a new monitoring and/or reporting regime for these review bodies. For example, in Australia, where a Human Research Ethics Committee has been established, they are encouraged to register with and report annually to the National Health and Medical Research Council.[[12]](#footnote-12)

### Fee-for-review

Some stakeholders have suggested that introducing a fee for review[[13]](#footnote-13) would ensure that more research gets ethical review and improve the sustainability of some of the newer structures. Introducing a fee for ethical review may mean that HRCEC approved committees could offer review to a broader range of researchers, for example, an institutional ethics committees might review research that has no connection to their organisation.

Australia’s National Health and Medical Research Council allow registered Human Research Ethics Committees to charge a fee for ethical review. Organisations or institutions that charge fees for the services of their registered Human Research Ethics Committee are responsible for developing a publicly available and comprehensive policy that includes the rates/fees, an explanation of how those rates were determined, who pays, and how the organisation will make use of the fee. Such a policy provides reassurance that the integrity of the process of ethical review is not compromised by charging a fee.

Charging a fee may also help with the sustainability of unaccredited alternative ethical review structures that cannot attain funding. A fee may help recoup some of the costs involved, and transparency around use of fees may help mitigate concerns that researchers could be 'paying for a result'.

### 3.5 Questions

1. What mix of HDECs and institutional ethics committees (both public and private sector) should be allowed or encouraged?
2. Should the emergence of ethics committees that are established by standalone businesses or trusts be allowed, or even encouraged?
3. Should alternative ethical review structures be monitored, and if so, who could do this?
4. What would an accreditation process for alternative review structures need to include to be credible?
5. Are there any other suggestions (apart from accreditation) for ensuring good governance frameworks and quality of review for ethical review structures?
6. What is the indemnity status of alternative ethical review structures?
7. Is the indemnity status a barrier to seeking ethical review from alternative structures?

## Peer review for scientific validity

### 4.1 Current ethics arrangements

The scientific validity[[14]](#footnote-14) of a research project is one component of ethically sound research. Good peer review processes serve to diminish risk but they also add value. Research with insufficient scientific validity will waste scarce resources, misuse the trust and commitment of participants, and may needlessly expose them to risk for little benefit. It is primarily the researcher’s responsibility to ensure that proposed research is scientifically valid. There are a range of different mechanisms for obtaining appropriate peer review.

Where the research involves the use of a new medicine, approval is required under section 30 of the Medicines Act 1981. Scientific assessment of clinical trials that involve the introduction of nucleic acids, genetically manipulated micro-organisms, or viruses or cells into human subjects is undertaken by the HRC’s Gene Technology Advisory Committee. For all other clinical trials involving a new medicine, scientific assessment is undertaken by the HRC’s Standing Committee on Therapeutic Trials.

For research that requires HDEC review, peer review must be completed before an application is made. HDECs are responsible for checking that appropriate peer review has been carried out. An HDEC may suggest additional peer review be carried out where it considers that the peer review for a study has not been sufficiently robust (eg, where the reviewer has a conflict of interest) or that the study may not be scientifically valid.

### 4.2 Issues

There are three main issues associated with scientific peer review:

* accessing peer review – it can be difficult for researchers to access appropriate peer review; this is particularly the case for researchers from smaller organisations with no internal peer review capacity
* adequacy of guidance – the type of peer review process must be fit-for-purpose but the current guidance does not set out what level of review is required for different types of research
* limitations of scientific peer review – as NEAC’s guidelines note, research may have a satisfactory assessment of scientific validity but still have ethical concerns because of how the research is to be operationalised; an ethics committee may not have the expertise required to identify all the ethical concerns associated with particular study designs and their execution.

### 4.3 Current responses

### Accessing scientific peer review

Different organisations have developed different processes for obtaining peer review.

* Some institutional ethics committees have members who are able to undertake scientific peer review, for example, the University of Otago Human Ethics Committee (Health) provides peer review for University of Otago applications.
* Health Research South (research partnership between the Dunedin School of Medicine and Southern DHB) has developed its own peer review process for all research projects involving human participants – guidelines set out the minimum requirements for peer review processes in individual departments of the Dunedin School of Medicine.
* The scientific quality of Auckland University of Technology student research proposals is assessed by the relevant study board when students are enrolled in the programme.
* In the Health Innovation Hub’s process of review, advice on innovation and device trials is provided by a reference group made up of clinicians and experts.

### Guidance

NEAC’s *Ethical Guidelines for Intervention Studies* and *Ethical Guidelines for Observational Studies* include guidance on features of robust peer review for assessing the scientific validity of research.

The scientific peer review template on the HDEC website provides guidance for researchers who are submitting applications for HDEC review. This document draws on the guidance in NEAC’s ethical guidelines, with the peer review template including guideline prompts under three areas of focus: the relative merit of the research, design and methods, and feasibility of the research.

### 4.4 Other possible responses

### Accessing scientific peer review

Some stakeholders have suggested that the peer review process for journal articles is a good model – it is a streamlined process, enables access to a wide range of peer reviewers (including internationally) and is transparent.

### Guidance

Further guidance could be developed on the peer review expectations for different types of research. For example, Health Research South’s guidelines for scientific peer review of research involving human participants describe three levels of peer review:

* Level A is required for HDEC and other ethics committee review and reflects the level of ethics risk and need for sound scientific justification, methodology and feasibility; this level of review is also expected for research where there is greater research complexity, resource investment and institutional risk.
* Level B is required for research not requiring HDEC review and recognises that some research has lower risk, complexity and investment of resource.
* Level C is required for confirming validity of research carried out for the purpose of learning to do research, there is no direct intent to gain new knowledge and ethics committee review is not required.

### Limitations of scientific peer review

One suggestion for addressing the lack of expertise on HDECs is to have a panel of independent peer reviewers that they could seek advice from, either on the peer review for a particular study or how the study will be operationalised.

### 4.5 Questions

1. What are the barriers to accessing scientific peer review?
2. What other options could be provided for researchers seeking scientific peer review?
3. What additional guidance on scientific peer review would be helpful?
4. What mechanisms could be available for HDECs to obtain advice on the scientific peer review of a proposed study?

## Audit and audit-related activity

### 5.1 Current ethics arrangements

The primary purpose of an audit or related activity is to improve delivery of the particular health or disability support service being studied or to control a threat to public health. There is an expectation that health professionals will undertake such activity to monitor the quality of their work.

The *Standard Operating Procedures* for HDECs state that an audit or related activity requires HDEC review **only if** it involves the use, collection or storage of human tissue without consent, other than in accordance with a statutory exception.[[15]](#footnote-15)

The *Standard Operating Procedures* rely on the definition as set out in NEAC’s *Ethical Guidelines for Observational Studies* (2012). These guidelines suggest that the major difference between audit and observational research is the primary purpose or justification for the activity:

* audit or related activity aims to improve delivery of the particular health or disability support service being studied or to control a threat to public health
* observational research aims to add to generalisable knowledge about a health or disability issue.

A summary of the 10 main types of audit and related activities were brought into NEAC’s guidelines following consultation feedback that definitions of ‘audit’ and ‘research’ require clarification. These are reproduced below.

|  |
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| **Audits** involve the systematic evaluation of aspects of health or disability support service delivery by considering measurable indicators of performance and/or quality.**Programme evaluation** is a type of audit where a whole programme is evaluated, rather than specific interventions.**Evaluation studies** aim to determine the relevance, effectiveness and impact of activities in the light of their objectives. Several types of evaluation are distinguished, including evaluation of the structure, process and outcome of an activity.**Quality assurance activities** aim to improve health and disability support services by assessing the adequacy of existing practice against a standard.**Outcome analyses** involve the assessment of health and disability support service quality by reviewing health care information to evaluate outcomes without comparing them against a standard. For example, clinicians may retrospectively examine health care notes and perform descriptive analyses to determine the outcome of medical treatment or course of a particular illness.**Benchmarking** aims to improve practice through the comparison of two or more health and disability support services.**Public health investigations** explore possible risks to public health, are often of an immediate or urgent nature, and are often required by legislation. Examples are investigations into outbreaks or clusters of disease, analyses of vaccine safety and effectiveness, and contact tracing of communicable conditions.**Public health surveillance** involves the monitoring of risks to health by methods that include the systematic collection, analysis and dissemination of information about disease rates.**Pharmacovigilance** (post-marketing surveillance) involves monitoring the adverse effects of pharmaceuticals after their introduction into the general population, by such methods as the spontaneous reporting of adverse events and the monitoring of all adverse events for a restricted group of medicines (prescription event monitoring).**Resource utilisation reviews** evaluate the use of resources in a particular health or disability service activity, for example, by reviewing health records to determine health care inputs such as chest X-rays for patients with a particular diagnosis. |

### 5.2 Issues

NEAC’s review has found that there is some confusion around the definition of audit and related activity (as defined by NEAC’s guidelines) and therefore uncertainty about whether a researcher’s proposed activity requires HDEC review or not.

There is anecdotal evidence that ambiguity surrounding the distinction between observational research and audit may lead to:

* studies being declined for publication as the authors believed they were undertaking audit and had not sought HDEC approval, whereas journal editors considered it to be research that lacked ethics approval
* researchers designating their activities as ‘audit’ so as to avoid HDEC review, illustrating the point that the apparent distinction between observational research and audit can be vague enough for a researcher to apply either definition to their activity.

Audit and other related activity can employ methods similar to those used in observational research and have the potential to raise the same ethical issues. The difficulty in creating definitions that clearly separate ‘quality assurance’ from ‘clinical research’ has been internationally recognised. [[16]](#footnote-16)

### 5.3 Current responses

There are no other national-level definitions of audit and observational research that can help to guide researchers. The Code of Health and Disability Services Consumers’ Rights 1996 makes a distinction between research and external audit or evaluation of services but does not define these terms.

The Ministry’s HDEC secretariat is available to provide assistance to researchers to help determine which activities are classified as audit and therefore do not require HDEC review but there is limited capacity for this level of individual assistance.

Similarly, the Awhina Research and Knowledge Centre at Waitemata DHB provides assistance to researchers where there is uncertainty about how their research should be classified. The Centre indicates that this is not infrequent and questions often arise when new information is being collected or data held by other organisations are being combined with data held by Waitemata DHB.

### 5.4 Other possible responses

### Clarify distinction between audit and observational research

NEAC could review the definitions of audit and audit-related activity in its review of *Ethical Guidelines for Observational Studies.* Feedback suggests that, in practice, a distinction based on purpose is arbitrary and not helpful for determining need for ethical review. Other factors may be more critical.

For example, the NEAC guidelines distinguish between case studies (a type of observational research) and outcome analysis (a type of audit) on the basis of the purpose or intent of the activity. However, both activities involve access to (usually identifiable) information for a secondary purpose to which it was originally collected and so both meet the minimal risk threshold for review, but only case studies are subjected to HDEC review (because it is observational research and is able to meet the criteria for review).

The UK’s National Research Ethics Service sets out four criteria to help distinguish between research and audit – intent, use of an intervention, allocation of treatment and randomisation. However these criteria focus on clinical research as opposed to observational research. Some institutional review boards in the United States define research according to whether the results will be publishable. It is argued, however, that this criterion is inappropriate, because journals regularly publish reports about audit activities (Ogrinc, Nelson, Adams, & O’Hara, 2013).[[17]](#footnote-17)

Ogrinc et al (2013) have developed and tested a checklist instrument to distinguish between quality improvement and clinical research (including qualitative research), including whether any quality improvement activity includes aspects of research and warrants ethical review. Six key attributes help distinguish between audit and research:

1. intent
2. methods
3. intended benefits
4. risk
5. applicability of results
6. sharing and disseminating results.

Pilot testing of the instrument found that it was capable of clearly differentiating between audit and clinical research activities for proposals previously submitted to an ethics committee.

### Introduce a risk assessment approach for audit and related activity

Alternatively, a risk assessment approach could be used to help determine whether or not ethical review is required for audit and related activity. Where audit or a related activity is classified as more than minimal risk, it could either:

* prompt the researcher to seek further advice on the classification of their study, or
* trigger review by an ethics review body, such as an institutional ethics committee, or
* trigger review by an HDEC.

The threshold of risk would need to be clearly defined, with criteria for judging whether audit and related activity reaches the threshold. Such criteria could include:

1. new or additional information being sought
2. the detail and level of consent previously given by a patient
3. who will have access to what level and kind of information (eg, identifiable versus encrypted or anonymised data)
4. inclusion of vulnerable people
5. the level of risk involved.

If review by an HDEC was a favoured option, this would require an amendment to the *Standard Operating Procedures* for HDECs to allow for review of audit and related activity when it meets the threshold for minimal risk.

### 5.5 Questions for feedback

1. Does the current classification of studies into observational research and audit or related activity act as a barrier to audit and related activity?
2. Do you think the definition of audit could be improved, and if so, how?
3. How useful is it to classify studies into observational research and audit for the purposes of knowing whether or not ethical review is required?
4. Are there other international approaches for distinguishing between research and audit that have worked well?
5. Could a risk assessment approach be applied to observational studies when thinking about whether or not ethical review is required?

## 6. Innovative practice

### 6.1 Current ethics arrangements

NEAC’s *Ethical Guidelines for Intervention Studies* recognises the overlap between intervention studies and innovative practice. Innovative practice is defined as practice that is a planned deviation from currently accepted practice. The scope of NEAC’s guidelines includes innovative practice in the context of an intervention study. When intending to use an innovative practice, health professionals have an obligation to objectively evaluate its efficacy and safety. NEAC’s guidelines suggest that this is best done through an intervention study.

### 6.2 Issues

### Innovative practice or research?

Whether a practice is innovative depends on the extent of deviation from established practice. The significance of the deviation can be judged by its likely benefits and risks to subjects; where there is no good reason to expect that a deviation carries new benefits or risks, the deviation may be considered to lie within the scope of routine variation. The greater the risks and/or benefits of an innovative practice, the greater the value that could be gained from producing generalisable information through research. Some stakeholders have suggested that there is insufficient guidance to determine when:

* innovative practice is being undertaken in the context of an intervention study
* the efficacy and safety of an innovative practice needs to be evaluated through an intervention study.

### Ethical review of innovative practice

Stakeholders have raised questions about the adequacy of existing review processes for innovative practice (that is not an intervention study). In particular, there is a lack of clarity on current processes and inconsistency across DHBs. This issue was also raised by the Health and Disability Commissioner in a 2013 investigation into the prescribing of ketamine in Southern DHB.[[18]](#footnote-18)

### 6.3 Current responses

The DHB Chief Medical Officers’ Group has developed a national policy for all DHBs on the use of unapproved medicines and the use of medicines for unapproved indications (off-label use). In some cases, using medicines for unapproved indications may be considered to be innovative practice; in other cases, medicines may be in common use (eg, many medicines routinely used in paediatrics are not approved for use with children). The national policy work responded to recommendations by the Health and Disability Commissioner that all DHBs review their policy on off-label prescribing (Case 11HDC01072). This includes whether clinicians have a common understanding of what is meant by “well conducted clinical trials”, the meaning of innovative treatment, what precautions should be taken, what peer review is expected, how it should be recorded, at what point the concurrence from peer consultation is sufficiently positive, and what ethical consideration needs to occur with different levels of novel or unusual medications.

Otago University Human Ethics Committee (Health) has been approached by DHBs and asked to consider innovative practice applications. The Committee considers it may be appropriate for them to undertake this review but only where the DHB is linked with the University.

### 6.4 Other possible responses

NEAC could undertake further work to develop guidance on innovative practice with a particular focus on ethical issues and the circumstances in which innovative practice should be subject to an intervention study.

### 6.5 Questions

1. Should further guidance be developed on innovative practice?
2. What guidance on innovative practice would be helpful for health professionals?
3. What are your views on current processes for reviewing innovative practice?

## 7. Other issues

This discussion document sets out NEAC’s analysis of current cross-sectoral research ethics arrangements for health and disability research. It describes issues associated with six aspects of these ethics arrangements and discusses current and other possible responses. NEAC welcomes your feedback on these issues and responses.

There are likely to be other issues that are not covered in this document and NEAC would like to hear about these, along with any suggestions for addressing these issues.

### 7.1 Questions

1. What other issues are associated with the cross-sectoral ethics arrangements for health and disability research?
2. How might these issues be addressed?

# Appendix 1: Ethics review, advisory and monitoring bodies

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| Advisory Committee on Assisted Reproductive Technology | Established under section 32 of the Human Assisted Reproductive Technology Act 2004.Members are appointed by the Minister of Health. | * Issues guidelines and advice to the Ethics Advisory Committee on Assisted Reproductive Technology regarding assisted reproductive procedures or human reproductive research.
* Provides the Minister of Health with advice about such procedures or research.
 |
| Data Monitoring Core Committee (DMCC) | Administered by the HRCEC.Members are appointed by the HRC.  | * Independently reviews grant applications of clinical trials, innovative treatment evaluation or community intervention studies submitted to the HRC for research funding and makes recommendations on monitoring issues.
* Ensures HRC-funded trails requiring independent data and safety monitoring are adequately monitored, and if appropriate, constitutes trial-specific Data Monitoring Committees (DMCs).
* Evaluates, advises and contributes to other independent or international DMCs on those trials funded or co-funded by the HRC.
 |
| Ethics Advisory Committee on Assisted Reproductive Technology | Established under section 27 of the Human Assisted Reproductive Technology Act 2004. | * Considers and determines applications for assisted reproductive procedures and human reproductive research.
* Under the HART Act, it is an offence to carry out such procedures or research without prior written ethics committee approval.
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| Gene Technology Advisory Committee (GTAC) | Established by the HRC. | * Reviews proposals for clinical trials that involve introducing nucleic acids, genetically manipulated micro-organisms, or viruses or cells into human subjects.
* Makes recommendations to the Director-General of Health for an exemption under section 30 of the Medicines Act 1981 to allow trials related to gene therapy and other protocols involving administration of nucleic acids to proceed.
 |
| Health and Disability Ethics Committees (HDECs) | Ministerial committees established under section 11 of the New Zealand Public Health and Disability Act.There are four HDECs: Northern A, Northern B, Central and Southern. | * Secures the benefits of health and disability research by checking that it meets or exceeds established ethical standards.
* HDECs are required to act in accordance with the procedural rules and guidance contained in the Standard Operating Procedures for HDECs.
 |
| Health Research Council(HRC) | Established under the Health Research Council Act 1990. Members are appointed by the Minister of Health. | * Advises the Minister of Health on national health research policy and administers government funding for the purpose of implementing that policy.
* Supports research that has the potential to improve health outcomes and delivery of healthcare, and to produce economic gain for New Zealand.
 |
| Health Research Council Ethics Committee(HRCEC) | An HRC committee established under section 24 of the Health Research Council Act 1990. Members are appointed by the HRC. | * Ensures HRC-funded research has an independent ethical assessment by the HRCEC itself or by an ethics committee approved by the HRCEC.
* Approves ethics committees that conduct ethical review and provides advice about membership, procedures and standards for ethics committees.
* Provides final and binding decisions on HDECs for applicants appealing an HDEC decision to decline, suspend or cancel approval of a research application.
* Provides second opinions for an applicant or an ethics committee, on a proposal that has been submitted for ethical review to an accredited ethics committee.
* Provides independent comment on ethical problems that may arise in health research.
 |
| National Ethics Advisory Committee (NEAC) | Established under the New Zealand Public Health and Disability Act 2000. Members are appointed by the Minister of Health. | * Provides advice to the Minister of Health on ethical issues in health services and research.
* Determines national ethical standards across the health and disability sector.
 |
| Standing Committee on Therapeutic Trials (SCOTT) | Established by the HRC. | * Makes recommendations to the Director-General of Health on whether or not clinical trials that involve the use of a new medicine should be approved.
* Assesses whether or not the proposed clinical trial of a medicine will provide clinically and scientifically useful information, particularly in relation to the safety and efficacy of the agent.
* Assesses the ability of the triallists to conduct the trial and attempts to improve trial design and the quality of clinical pharmacological research.
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# Appendix 2: List of Stakeholders

NEAC met with representatives from the following organisations and groups:

* Research Office, Waitemata DHB
* Research Office, Counties Manukau DHB
* Health Research South
* New Zealand Association of Clinical Research
* Health and Disability Ethics Committee chairs
* Health Research Council Ethics Committee
* Auckland University of Technology Ethics Committee
* Otago University Ethics Committee
* Unitec Ethics Committee
* New Zealand Ethics Committee
* St Johns
* Families Commission
* Council of Medical Colleges
* DHB Clinical Ethics Advisory Groups
* Health Innovation Hub
* Ministry of Health

# Appendix 3: Guidelines and legislation

This appendix provides a brief description of ethical guidelines, international statements, legislation and codes that researchers need to be aware of when undertaking health and disability research.

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| New Zealand ethical guidelines  |
| Ethical Guidelines for Observational Studies (2012)Ethical Guidelines for Intervention Studies (2012)  | National Ethics Advisory Committee  | These guidelines set out the ethical standards that all researchers must meet when undertaking health and disability research. These guidelines are also of use to ethics committees, research sponsors and for training and educating researchers.  |
| Goals, Objectives, and Desired Outcomes for Ethical Review System (GODO) (2010) | National Ethics Advisory Committee | GODO states established goals, objectives and desired outcomes that are to be applied to the ethical review system.  |
| Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research (2006) | Ministry of Health | These guidelines outline requirements for New Zealand researchers using cells from established human embryonic stem cell lines in research, including mandatory ethical review of research applications.  |
| Guidelines in the Use of Human Tissue for Future Unspecified Research Purposes (2007) | Ministry of Health | These guidelines outline the consent and ethical review requirements for New Zealand researchers who wish to use human tissue for future unspecified research.  |
| Guidelines for Researchers on Health Research involving Māori (2010)  | Health Research Council  | These guidelines assist researchers undertaking biomedical, public health or clinical research involving Māori participants or research on issues relevant to Māori health. In particular, these guidelines inform researchers about consultation and the processes involved in initiating consultation with Māori.  |
| Te Ara Tika Guidelines for Māori Research Ethics: A framework for researchers and ethics committee members |  The Pūtairoa Writing Group, Health Research Council  | This document outlines a framework for addressing Māori ethical issues within the context of decision-making by ethics committee members. It draws on a foundation of tikanga Māori (Māori protocols and practices) and will be useful for researchers, ethics committee members and those who engage in consultation or advice about Māori ethical issues from a local, regional, national, and/or international perspective. |
| Pacific Health Research Guidelines (2014)  | Pacific Health Research Committee, Health Research Council  | These guidelines build on the principles outlined in the HRC's Guidelines on Pacific Health Research (2005), and address some of the fundamental issues relating to contemporary Pacific health research in an evolving global environment. |
| Researched Medicines Industry Guidelineson Clinical Trials Compensation for Injury Resulting From Participation in an Industry-Sponsored Clinical Trial(2008) | Researched Medicines Industry Association of New Zealand Inc.  | These guidelines outline principles for compensation for injury caused by participation in clinical trials. They are aimed at companies sponsoring clinical trials.  |

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| International guidelines  |
| Declaration of Helsinki: Ethical principles for medical research involving human subjects (2008)  | World Medical Association | The Declaration of Helsinki is a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. It is primarily aimed at physicians but the World Medical Association encourages others who are involved in medical research involving human subjects to adopt these principles. |
| ICH Harmonised Tripartite Guidelines: Guideline for good clinical practice (1996) | The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) | This document describes the responsibilities and expectations of all participants in the conduct of clinical trials, including investigators, monitors, sponsors and review bodies. |
| International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) | Council for International Organizations of Medical Sciences and World Health Organization  | These guidelines are designed to be of use in defining national policies on the ethics of biomedical research, applying ethical standards in local circumstances, and establishing or redefining adequate mechanisms for ethical review of research involving human subjects. |
| International Ethical Guidelines on Epidemiological Studies (1999) | Council for International Organizations of Medical Sciences | These guidelines are intended to draw the attention of investigators, sponsors and ethical review committees to the need to consider carefully the ethical implications of research protocols and the manner in which epidemiological research is conducted. |
| Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (2013) | International Committee of Medical Journal Editors  | These recommendations review best practice and ethical standards in the conduct and reporting of research and other material published in medical journals. They aim to help authors, editors, and others involved in peer review and biomedical publishing create and distribute accurate, clear, unbiased medical journal articles.  |

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| Legislation  |
| Accident Compensation Act 2001 | The Accident Compensation Act governs injury prevention, rehabilitation, and compensation; and establishes the Code of Accident Compensation Corporation (ACC) Claimant’s Rights.  | The Act covers some treatment injuries in clinical trials.The Act specifically excludes from ACC cover any treatment injury from any trial that is conducted ‘principally for the benefit of the manufacturer or distributor of the medicine or item being trialled’. (Section 32 (6)) |
| Care of Children Act 2004 | The Care of Children Act provides guidance on the care and custody of children and young people; promotes children’s welfare and best interests; and recognises certain rights of children. | The Act governs consent to any medical, surgical or dental procedures in relation to a child. (Section 36) |
| Code of Health and Disability Services Consumers’ Rights 1996 (the Code of Rights) | The Code of Rights grants rights to all consumers of health and disability services in New Zealand, and places corresponding obligations on providers of those services. The Code of Rights is a regulation under the Health and Disability Commission Act 1994 (section 74). | The rights in the Code of Rights extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, research.  |
| Health and Disability Commissioner Act 1994 | The Health and Disability Commissioner Act establishes the Health and Disability Commissioner and facilitates the resolution of complaints relating to infringements of the rights of health and disability consumers.  | The Act gives the Health and Disability Commissioner powers to investigate, a complaint or on the Commissioner’s own initiative, any action that may be in breach of the Code of Rights, including in the context of research.  |
| Health Information Privacy Code 1994 | The Health Information Privacy Code sets specific rules for agencies in the health sector. The 12 rules regulate how health agencies (such as doctors, health insurers and District Health Boards) may collect, hold, use and disclose health information about identifiable individuals. The Code is established under Part 6 of the Privacy Act 1993.  | The rules in the Code apply to research that uses identifiable health information. Rule 5 (storage and security of health information) and Rule 11 (limits on disclosure of health information) are particularly relevant to observational research.  |
| Human Assisted Reproductive Technology Act 2004 |  The Human Assisted Reproductive Technology Act regulates assisted reproductive procedures and human reproductive research.   | The Act requires that human reproductive research only be conducted on an individual where the individual has made an informed choice and given informed consent. Human reproductive research must be approved by the Ethics Committee on Assisted Reproductive Technology and approved research must be undertaken in accordance with the guidelines issued by the Advisory Committee of Human Reproductive Technology.  |
| Human Tissue Act 1998  | The Human Tissue Act regulates the collection, supply, and trade of human tissue and human tissue products in New Zealand.  | The Act specifies the circumstances when human tissue may be collected and used with and without informed consent, and specifies the processes of informed consent (sections 9, 14, 19, 21, 22, 24 and 31).  |
| Medicines Act 1981 | The Medicines Act regulates medicines, related products and medical devices in New Zealand. The Act ensures that the medicines and products used in New Zealand are safe and effective. | The Gene Technology Advisory Committee makes recommendations to the Director-General of Health for an exemption under section 30 of the Act to allow trials related to gene therapy and other protocols involving administration of nucleic acids to proceed.Under section 30 of the Act the Standing Committee on Therapeutic Trials makes recommendations to the Director-General of Health on whether or not clinical trials that involve the use of a new medicine should be approved. |
| New Zealand Bill of Rights Act 1990  | The Bill of Rights Act sets out the rights and fundamental freedoms of anyone subject to New Zealand law.  | The Bill of Rights applies to a person being physically involved in research (as opposed to using their health information). Under the Act every person has the right not to be subject to medical or scientific experimentation without that person’s consent (section 10) and everyone has the right to refuse to undergo any medical treatment (section 11).  |
| Privacy Act 1993 | The Privacy Act regulates how public and private sector agencies may collect, hold, use and disclose personal information about identifiable individuals.  | The Act specifies 12 information privacy principles. In particular, principle 5 governs the way personal information is stored and principle 11 places restrictions on how people and organisations can disclose personal information.  |
| Protection of Personal and Property Rights Act 1988 | The Protection of Personal and Property Rights Act provides for the protection and promotion of the personal and property rights of those who are no longer fully able to manage their own affairs.  | The Act permits a welfare guardian to consent on behalf of a person without capacity to take part in research that is conducted for the purpose of saving their life or preventing serious damage to that person’s health (section 18).  |

# Appendix 4: NEAC’s Goals, Objectives and Desired Outcomes of an Ethical Review System

The National Ethics Advisory Committee – Kāhui Matatika o te Motu (NEAC) has issued a statement of *Goals, Objectives, and Desired Outcomes of an Ethical Review System* (GODO) in accordance with its statutory function to ‘determine nationally consistent ethical standards across the health sector’ (New Zealand Public Health and Disability Act 2000, s.16).

The ethical review system includes ethical aspects of self-review, peer review, ethics committee review, and specialist review of health and disability research and related activity. It applies established ethical standards to research and related activity. GODO states established goals, objectives and desired outcomes that are to be applied to the ethical review system itself.

|  |
| --- |
| **Overall Goals** |
| * Facilitate research and innovative practice that contributes to knowledge and improved health outcomes
* Protect participants in health and disability research and innovative treatment
* Find a balance that minimises risks and maximises benefits arising from health and disability research
* Recognise and respect the principles of the Treaty of Waitangi by enabling Māori to contribute to the ethical review system for health and disability research
 |
| **Objectives** | **Desired outcomes** |
| **Accountable** | * Public accountability requirements are defined.
* Ethical reviews meet internationally recognised standards.
* Ethical reviews take into account relevant legislation.
 |
| **Enabling** | * Research participants/subjects are protected.
* Quality research is facilitated.
* Review processes are clear about jurisdiction and coverage.
* Awareness of ethical practice among all stakeholders is developed.
* Good communication with affected communities is demonstrated.
* Local input is achieved.
* Positive relationships with all stakeholders are developed.
* System review mechanisms are in place.
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| **Informed** | * Researchers consider ethical implications from the outset; eg, there is clarification of who will benefit from the research (participants, the public, etc.).
* The perspectives of affected communities are included.
* Review processes are proactive and attend to emergent issues, and are responsive to change over time.
* Review processes apply appropriate expertise.
* Scientific and ethical standards are considered alongside each other where appropriate.
* Decision-making is consistent.
* Review capacity and relevant expertise are maintained and developed
 |
| **Enabling of Māori participation** | * A Māori ethical framework is developed and implemented.
* Consultation with Māori is collaborative, genuine, inclusive, and appropriate.
* Māori participation in the decision-making component of the system is facilitated.
* The potential for diversity of opinion across iwi and regions is recognised and respected.
* Māori research capability is facilitated.
 |
| **Fair** | * Review processes are independent.
* Stakeholders have access to due process.
* Outcomes of processes are equitable.
* Applicants to review processes have the right of reply.
* Conflicts of interest are acknowledged and addressed.
 |
| **Efficient** | * Time and resources are used productively.
* Reviews are timely.
* Sector guidance is updated regularly, with opportunity for all stakeholders to participate.
 |

1. Goals, objectives and desired outcomes (NEAC, 2010) http://neac.health.govt.nz/system/files/documents/publications/neac-godo-statement.pdf [↑](#footnote-ref-1)
2. <http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval>

 [↑](#footnote-ref-2)
3. The National Research Authority aims to protect and promote the interests of patients and the public in research, and to streamline the regulation of research. Its website is <http://www.hra.nhs.uk/research-community/> [↑](#footnote-ref-3)
4. Health Research Council. 2010. *Guidelines for Researchers on Health Research Involving Māori*. URL: [http://www.hrc.govt.nz/sites/default/files/Guidelines%20for%20HR%20on%20Maori-%20Jul10%20revised%20for%20Te%20Ara%20Tika%20v2%20FINAL[1].pdf](http://www.hrc.govt.nz/sites/default/files/Guidelines%20for%20HR%20on%20Maori-%20Jul10%20revised%20for%20Te%20Ara%20Tika%20v2%20FINAL%5B1%5D.pdf) (accessed 22 September 2014) [↑](#footnote-ref-4)
5. Health Research Council. 2005. *Guidelines on Ethics in Health Research*. URL: <http://www.hrc.govt.nz/sites/default/files/Ethics%20Guidelines%20Oct%202005%20-%20under%20review_0.pdf> (accessed 22 September 2014) [↑](#footnote-ref-5)
6. Hudson M, Milne M, Reynolds P, Russell K, Smith B. 2010. *Te Ara Tika: Guidelines for Māori Research Ethics: A framework for researchers and ethics committee members.* Auckland: Health Research Council on behalf of the Pūtaiora Writing Group. [↑](#footnote-ref-6)
7. Refers to genealogy, lineage and descent. [↑](#footnote-ref-7)
8. See footnote 6. [↑](#footnote-ref-8)
9. Refers to Māori customs or protocols. [↑](#footnote-ref-9)
10. Smith B. 2014. Māori-centred codes of ethics: championing inclusiveness in creating professional codes of ethics across the New Zealand health sector. *The New Zealand Medical Journal* 127(1397): 9-12.URL: http://journal.nzma.org.nz/journal/127-1397/6192/ [↑](#footnote-ref-10)
11. Māori review advice on HDEC website <http://ethics.health.govt.nz/> (accessed 22 September 2014). [↑](#footnote-ref-11)
12. http://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs/hrec-annual-reporting-nhmrc [↑](#footnote-ref-12)
13. The Standing Committee on Therapeutic Trials charges $6,500 per review. [↑](#footnote-ref-13)
14. Scientific validity, in a broad sense, is the validity of the research within the terms of the particular research paradigm. Peer review to determine scientific validity should consider the relative merit of the research, quality of study design and methods, and the feasibility of the research. [↑](#footnote-ref-14)
15. Section 20(f) of the Human Tissue Act 2008 and Right 7(10)(c) of the Code of Health and Disability Services Consumers’ Rights 1996 [↑](#footnote-ref-15)
16. National Health and Medical Research Council (NHMRC). 2003. *When Does Quality Assurance in*

*Health Care Require Independent Ethical Review?* Canberra: National Health and Medical Research <http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e46.pdf> [↑](#footnote-ref-16)
17. Ogrinc, Nelson, Adams, O’Hara, “An instrument to differentiate between clinical research and quality improvements, IRB: Ethics & Human Research, 35 (5), pp 1-8. [↑](#footnote-ref-17)
18. Case 11HDC01072. [↑](#footnote-ref-18)