



Health Research
Council of
New Zealand
Te Kaunihera Rangahau Hauora o Aotearoa

September 2017

HRC Research Ethics Guidelines *(Guidelines)*

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1. Overview

1.1 Introduction

The national system of ethics review is comprised of a number of committees with various responsibilities for human ethics and animal ethics.

1.1.1 *The Treaty of Waitangi*

The Treaty is the founding document of New Zealand. The principles of partnership and sharing implicit in the Treaty should be respected by all in all health research proposals.

1.1.2 *Human ethics*

- (a) The following ethics committees are established under statute:
- i. The Health Research Council Ethics Committee, see **1.2 HRC EC**;
 - ii. The National Ethics Advisory Committee, see **1.3 NEAC**;
 - iii. The Ethics Committee on Assisted Reproductive Technology, see **1.4 ECART**, and
 - iv. The Health and Disability Ethics Committees, see **1.5 HDECs**.
- (b) Ethics committees set up by organisations and which may also be approved by the HRC EC include Institutional Ethics Committees (IEC).

See **1.7 Approved ethics committees** for the list of HRC approved ethics committees.

1.1.3 *Animal ethics*

The framework for animal ethics is set out in the Animal Welfare Act 1999.

For more information on research involving animals or animal materials, see **3.16**.

1.2 Health Research Council Ethics Committee (HRC EC)

The HRC EC is an HRC statutory committee established under section 24 of the [Health Research Council \(HRC\) Act 1990](#).

The HRC EC requires that, prior to commencing research; all HRC funded research has received ethics approval. Avenues for ethical comment on HRC funded research have been established by the HRC EC through the delegated authority given to approved health and disability or institutional ethics committees.

The HRC EC will also consider appeals against the decisions of Health and Disability Ethics Committees, a role required of it by the Minister of Health, under section 25(h)ii of the HRC Act 1990.

For more information on appeal, see **2.7.3**.

1.2.1 Functions

The functions of the HRC EC are set out in section 25 of the HRC Act and include the following:

- (a) To consider and make recommendations to the Council on ethical issues in relation to health research, especially those emerging through the development of new areas of health research.
- (b) To provide and review ethical guidelines for the Council.
- (c) Subject to paragraph (d), to ensure that, in respect of each application submitted to the Council for a grant for the purposes of health research, an independent ethical assessment of the proposed health research is made either by the Ethics Committee itself or by a committee approved by the Ethics Committee.
- (d) Where an application for a grant for the purposes of health research is submitted to the Council in respect of health research that is of national importance or great complexity, to itself make an independent ethical assessment of the proposed health research.
- (e) To review, at the request of any person who has made an application for a grant for the purposes of health research, the independent ethical assessment made, in respect of the proposed health research, by a committee approved under paragraph (c).
- (f) To give, in relation to ethics committees established by other bodies, advice on –
 - i. the membership of those committees; and
 - ii. the procedures to be adopted and the standards to be observed, by those committees.
- (g) To provide independent comment on ethical problems that may arise in any aspect of health research.
- (h) To perform any other functions (whether or not related to health research) it is for the time being –
 - i. given by or under any enactment; or
 - ii. authorised to perform by the Minister, by written notice to the Health Research Council after consultation with it.

Additional responsibilities may be undertaken after discussion and agreement with the National Ethics Advisory Committee.

1.2.2 Membership

Members of the HRC EC are appointed by the Board of the HRC.

Membership is set out in section 26 of the HRC Act and must include the Chairperson of the Board or his/her nominee and one other member of the Board with qualifications in science. Five other persons, who are not members of the Board, are appointed having regard to the need to have a diversity of knowledge and experience in relation to science, ethics, philosophy, law, theology, nursing, women's health, patient advocacy and tikanga Māori.

The Chair of the HRC EC is appointed by the members of the HRC EC.

During 1992, the Board resolved that the maximum term of membership for HRC EC members will be three years plus possible renewal for up to a further three years.

1.3 National Ethics Advisory Committee (NEAC)

[NEAC](#) is a ministerial advisory committee established under section 16 of the New Zealand Public Health and Disability Act 2000 to advise the Minister of Health on ethical issues in health services and research, and determine national ethical standards for the health sector.

1.4 Ethics Committee on Assisted Reproductive Technology (ECART)

[ECART](#) is a ministerial committee established under section 27 of the Human Assisted Reproductive Technology (HART) Act 2004 that reviews, determines and monitors applications for assisted reproductive procedures and human reproductive research.

ECART can only consider applications for procedures that the Advisory Committee on Assisted Reproductive Technology ([ACART](#)) has issued guidelines and advice for.

1.5 Health and Disability Ethics Committees (HDECs)

[HDECs](#) are established under section 11 of the New Zealand Public Health and Disability Act 2000. The Committees are administered by the Ministry of Health.

The function of an HDEC is to secure the benefits of health and disability research by checking that it meets or exceeds established ethical standards set out in the guidelines authored by NEAC, namely: [Ethical Guidelines for Observational Studies](#) and [Ethical Guidelines for Intervention Studies](#). HDECs operate in accordance with the Standard Operating Procedures for HDECs: <http://ethics.health.govt.nz/operating-procedures>

1.6 Approval by HRC EC

It is the responsibility of the HRC EC to ensure that an independent ethical assessment of any proposed health research submitted for a HRC grant has been carried out either by the HRC EC itself, or an ethics committee approved by the HRC (see s25 of the HRC Act 1990). The HRC EC approves ethics committees to carry out this function (see **1.7 Approved Ethics Committees**).

Approved ethics committees also meet the conditions required to conduct ethical review for the following purposes:

- (a) to provide coverage of participants in a clinical trial who sustain injury, under [Accident Compensation Act 2001](#);
- (b) to allow disclosure of health information for research where it is either not desirable or not practicable to obtain authorisation from the individual concerned under the [Health Information Privacy Code 1994](#); and
- (c) to allow access to data held by the New Zealand Health Information Service database (NZHIS) in accordance with the Current Data Access Policy.

The approval of ethics committees by the HRC EC is a formal process. The HRC EC requires every approved ethics committee to provide an Annual report plus any other relevant

information required as stated in the [HRC Guidelines for Approval of Ethics Committees](#). Annual reports are due within three months of the reporting year end.

In re-approval year (a maximum of three calendar years from approval) a Report for seeking re-approval which addresses the performance and functioning of the committee over the last approval period must be submitted.

1.7 Approved ethics committees

1.7.1 *Institutional ethics committees*

(As of 30 September 2017)

Auckland Health Research Ethics Committee
(until 31 December 2019)

Auckland University of Technology Ethics Committee *(until 31 December 2018)* <http://www.aut.ac.nz/research/research-ethics>

Lincoln University Human Ethics Committee *(until 31 December 2019)* <http://www.lincoln.ac.nz/Research-at-Lincoln/Ethics/Human-ethics/>

Massey University Human Ethics Committee: Northern *(until 31 December 2019)* <http://www.massey.ac.nz/massey/research/research-ethics/human-ethics/>

Massey University Human Ethics Committee: Southern A *(until 31 December 2019)*

Massey University Human Ethics Committee: Southern B *(until 31 December 2019)*

UNITEC Research Ethics Committee *(until 31 December 2019)* <http://www.unitec.ac.nz/?DE4A5BB7-704A-4C5C-93B4-FE562A75B496>

University of Auckland Human Participants Ethics Committee *(until 31 December 2019)* <http://www.auckland.ac.nz/uoa/re-uahpec>

University of Otago Human Ethics Committee *(until 31 December 2019)* <http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html>

University of Otago Human Ethics Committee (Health) *(until 3 December 2019)*

University of Waikato Human Research Ethics Committee (Health) *(until 8 June 2018)* <http://www.waikato.ac.nz/research-enterprise/ethics/human-ethics-research-committee>

WINTEC Human Ethics in Research Committee *(until 31 December 2018)* <http://www.wintec.ac.nz/>

1.7.2 Health and disability ethics committees

(As of 30 September 2017)

Central Health and Disability Ethics Committee
(until 30 June 2018)

<http://www.ethics.health.govt.nz/>

Northern A Health and Disability Ethics Committee
(until 30 June 2018)

<http://www.ethics.health.govt.nz/>

Northern B Health and Disability Ethics Committee
(until 30 June 2018)

<http://www.ethics.health.govt.nz/>

Southern Health and Disability Ethics Committee
(until 30 June 2018)

<http://www.ethics.health.govt.nz/>

1.8 Resource documents relevant to research ethics

1.8.1 New Zealand Acts of Parliament

Accident Compensation Act 2001

Animal Welfare Act 1999

Health and Disability Commissioner Act 1994

Health Research Council Act 1990

Human Assisted Reproductive Technology Act 2004

Human Tissues Act 2008

Medicines Act 1981

New Zealand Public Health and Disability Act 2000

New Zealand Bill of Rights Act 1990

Privacy Act 1993

1.8.2 New Zealand guidelines, regulations and documents

Ethical Guidelines for Intervention Studies. National Ethics Advisory Committee (2012).

Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities. National Ethics Advisory Committee (2012).

Good Clinical Research Practice Guideline (Part 11 of the Guideline on the Regulation of Therapeutic Products in New Zealand). Medsafe, Ministry of Health (2011).

Guidelines for Researchers on Health Research Involving Māori. Health Research Council of New Zealand (2010 version 2)

HRC Research Ethics Guidelines

Guidelines for the Use of Human tissue for Future Unspecified Research Purposes. Ministry of Health (2007).

Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research. Ministry of Health (2006).

Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996.

Health Information Privacy Code 1994.

HRC Guidelines for Approval of Ethics Committees. Health Research Council of New Zealand (2012).

Non-Therapeutic use of Human Tissue NZS 8135:2009. Standards New Zealand (2009).

Pacific Health Research Guidelines. Health Research Council of New Zealand (2014)

Te Ara Tika: Guidelines for Māori Research Ethics: A framework for researchers and ethics committee members. Pūtaiora Writing Group (2010).

2. Matters relating to ethical review

The HRC expects investigators to conduct and report their work with objectivity and scientific honesty.

The HRC, as a public funder of research, expects researchers to share primary research data with valid secondary users where appropriate and having given due consideration to ethical, social and other issues. Dissemination, including peer reviewed publication, of research results in a manner that allows open access is encouraged by the HRC.

As part of their obligation to research participants, the investigators should ensure that the results of their research and an account of the methods employed are adequately and appropriately disseminated in a manner accessible to the research participants and to the public as well as to the scientific community.

Investigators should refrain from making claims or advancing conclusions that are not supported by evidence. Investigators should also recognise the boundaries of their professional competence and should not undertake research of a kind that they are not qualified to carry out.

Protection of the welfare of human participants is a basic principle of ethical review of research. There is a need to balance potential risk of harm to individuals with the possible benefits to society at large. On occasions when there are major issues, there should be broader discussion with the community.

When investigators are considering enrolment of persons in research studies, clinical trials or social surveys, the investigators should take into account any other research protocols involving the same individual which may already be in progress.

The HRC EC requires investigators to review the ethics of their research at least annually or, where appropriate, more frequently. As part of such a review, the investigator should consider the outcome or development of similar research conducted elsewhere whether in NZ or overseas. If significant variations to the research proposal are to be made, or the interim results of the research indicate that it may not be ethical to continue, the principal investigator should approach the ethics committee which approved the research proposal for its comment and further discussion before undertaking any continuation of the research.

2.1 Principles for research involving human participants

A number of principles should guide research that involves human participants. For a general statement of the principles, applicants should consult the [Declaration of Helsinki](#). These principles include, but are not limited to, the following, which will be used by ethics committees to assess research proposals:

2.1.1 *Informed consent*

The ethical foundation of informed consent is respect for persons. Researchers thus should make themselves familiar with the provisions of the [Code of Health and Disability Consumers' Rights](#).

Informed consent is required from participants involved in human research especially if the research constitutes a health care procedure. If informed consent cannot be obtained in writing, the circumstances under which consent was obtained should be recorded. If the participants

themselves cannot provide informed consent, justification must be provided for using these participants within the research. Ethics committees will be required to consider if the circumstances are appropriate for the waiving of informed consent. In cases where deception is used in research, justification must be provided as well as a method of debriefing participants.

Some of the basic criteria of informed consent to participate in a health research are:

- (a) the participants must be competent to understand the relevant issues prior to giving to their specific consent;
- (b) information about the proposed research must be comprehensively, properly and appropriately given, including any likely outcomes of participation in the research;
- (c) the participants' consent must be voluntary and not unduly influenced by financial reward (see **2.1.5 Payments for Participation in Research**), or by duress in any manner and the involvement of dependent or vulnerable groups must be appropriate with measures in place to ensure they are not exploited;
- (d) participants must be able to withdraw from the research at any time without the waiver of any rights and without giving reasons; and
- (e) in the case of those who are unable to give their own consent, for example the mentally incapacitated, the unconscious patient or children, proxy consent should be sought from a person with appropriate legal authority¹.

2.1.2 Scientific design and conduct of the study

Lack of scientific quality in any research project has ethical implications. Research with insufficient scientific merit will waste scarce resources, will abuse the trust and commitment of participants, and may needlessly expose them to risk for no appropriate benefit. Ethics committees should verify that the scientific quality of proposed research has been assured through an appropriate peer review process. For more guidance on features of robust peer review for assessing the scientific validity of research, see *Appendix 1* in [Ethical Guidelines for Observational Studies](#) or [Ethical Guidelines for Intervention Studies](#).

2.1.3 Risks and potential benefits

The risks of the research should be reasonable in relation to the potential benefits. Risks can be physical, emotional, social, psychological, or financial. Ethics committees should make sure that the proposed research poses minimal potential harms and negative impacts to participants. Ethics committees should also be aware that harm may occur at an individual, family or population level.

2.1.4 Selection of study population and recruitment of research participants

No group or class of persons should bear more than its fair share of the burdens of participation in research, nor should any group or class be deprived of its fair share of the benefits of research. Ethics committees should consider whether the study population will directly benefit

¹ In the case of research participants who are children the signature of the parent or guardian should be obtained in addition to the child's assent (see **section 3.7 Research involving children**).

from participating in the research or indirectly benefit from the new knowledge derived from the research.

Recruitment of research participants should be free from manipulation, coercion, deception, inducement or any other undue influence. Participants should be told the purpose of the research, the risks and benefits in participation and other relevant details that form the basis of informed consent.

2.1.5 Payments for participation in research

Any payment, koha or gift of money, goods or services to a research participant or to a body or organisation assisting in the recruitment of participants, which constitutes an undue inducement to participate in the research, is unacceptable.

Reimbursement for participants' out-of-pocket expenses (e.g. taxi fares, meals, parking fees) or in compensation for inconvenience caused through their participation in the research may be made. Payments for inconvenience would typically be a nominal amount in recognition of the effort of the participant to attend the research project.

2.1.6 Protection of research participants' privacy and confidentiality

The privacy and confidentiality of research participants must be respected. In particular, ethics committees have to be familiar with the [Privacy Act 1993](#) and the [Health Information Privacy Code 1994](#) when examining precautions taken to safeguard the privacy and confidentiality of research participants.

2.1.7 Cultural responsiveness

All health research is located within cultural settings that have evolved in the social and historical context within which the research is undertaken. It is important that research teams/units/institutions/communities reflect on the cultural perspectives of their organisations and workplaces in the broadest sense, as these perspectives influence the attitudes and behaviours that are brought into the research environment.

Within New Zealand, health research is likely to impact on Māori people and their communities. To this end, research teams/units/institutions/communities should specifically identify how their research will support indigenous health gains, and demonstrate a commitment to the principles of the Treaty of Waitangi.

All research teams/units/institutions/communities need to identify how their own beliefs and value systems may differ from those they wish to involve in their research. This will require having clear processes and procedures in place that allow for the inclusion of different cultural values and beliefs within the research agenda. This will provide other cultural groups and their viewpoints with the ability to influence the way in which the research problem is defined and thus the way the research is designed, conducted, analysed and disseminated. Such a process is more likely to lead to research that is responsive to the communities and/or populations involved which, in turn, should lead to better health gains for these communities and populations.

Ethics committees should ensure that all research involving human participants meets ethical standards that comply with international best practice. Best practice includes the expectation that researchers meaningfully consult with participants of research about the study question(s), design and conduct of the research. As well as the HRC Research Ethics Guidelines, applicants

should refer to the [HRC Guidelines for Researchers on Health Research involving Māori](#), and the [Guidelines for Pacific Health Research](#).

2.2 Research requiring ethics approval

Under the requirements of sections 25 and 31 of the Health Research Council Act 1990, every application approved for funding by the HRC must obtain independent ethics approval.

2.3 Scope of ethics committee review

A broad and common sense approach is to be adopted in interpreting “health research study” to ensure adequate protections for all participants. In this context, “health research study” includes epidemiological research, and may include various types of research where contact with participants could cause harm.

The primary and over-riding guideline is that applications should be reviewed by an approved ethics committee with the expertise required to evaluate the application, and to identify risks and the adequacy of protections for participants.

- (a) The scope of research that should be reviewed by an HDEC is explained in *Chapter 3*, the *Standard operating procedures of Health and Disability Ethics Committee* (the [SOPs](#)).
- (b) Ethics committees must ensure that members of their committees possess the appropriate expertise required for reviewing the kinds of research studies that are submitted to them, and possess the ability to identify whether adequate protections are in place for participants. Ethics committees reviewing health research would normally be expected to have a minimum of two registered health professionals with the appropriate expertise (at least one clinically trained and at least one in active practice).
- (c) In some circumstances, an IEC is the most appropriate committee to review the application if that research falls outside the scope of the HDEC.
- (d) Ethics approval for a research proposal must be obtained from a single approved ethics committee which is able to review a research proposal as a whole.
- (e) It is recognised that there may be limited circumstances where an IEC and an HDEC may each separately wish to review a particular research study. The policies and procedures of the committees should clearly specify those circumstances, and should identify which committee is to give the final approval in the circumstances.
- (f) The collection of human tissues to form part of an institutional anatomical collection should be dealt with in accordance with the [Human Tissue Act 2008](#) (see **3.6 Collection and use of human materials** and the [SOPs Chapter 13](#)).
- (g) It is recognised that cases may arise where exceptions to these guidelines may have to be considered and so the HRC EC should be informed accordingly in order that they can be discussed when future reviews and revisions of the guidelines are undertaken.

2.4 Special case HRC contracts

2.4.1 *Preliminary work under an HRC contract*

The HRC may permit a contract for the purpose of a pilot study or research development to commence prior to receipt of ethics approval if it is clear that the funding is to enable development of the research proposal to a state where it will be submitted for ethics approval, or for the training of personnel undertaking the study. Research may not commence until evidence of ethics approval is received by the HRC.

2.4.2 *Research contracts*

The HRC recognises that in the case of lengthy research studies, such as programme contracts, it may not be possible or feasible for the investigator to fully anticipate the ultimate direction the research will take when applying for the contract. In such situations the committee may allow the research to commence when ethics approval for the first stage of the research has been obtained. Ethics approval for ongoing research resulting from this earlier portion of the study must be subsequently obtained following appropriate review of the latest iteration of the research proposed.

2.4.3 *Career development contracts (CDAs)*

The HRC accepts that, in the case of some CDAs, a significant portion of training may be undertaken by the fellow or scholar before commencement of the research itself. A part of this training in research may comprise a detailed development of the research proposal, and the submission of that proposal for ethics approval. In such situations, funding for the training portion of a HRC Fellowship or Scholarship may commence before ethics approval for the research proposal is received. However, the research may not commence until evidence of ethics approval for the research has been received by the HRC.

Fellows or scholars undertaking HRC-funded research overseas are required to provide evidence of appropriate ethics approval (see **3.10 International Collaborations**).

2.5 How to obtain ethics approval

The HRC EC considers that ethics approval is best sought before submitting an application to the HRC, but accepts that this may not always be possible. Every application for HRC funding must contain a fully signed ethical agreement page, which attests that appropriate ethics approval for the research has been or will be obtained.

No application approved for funding by the HRC will have funds released until evidence of ethics approval, from an approved ethics committee, is received.

To ensure proper ethical review, ethics approval for a research proposal must be obtained from a single approved ethics committee able to review the research proposal as a whole. It must not be obtained in selected parts from more than one ethics committee. For example, where part of a research proposal falls under the scope of HDEC review (see the [SOPs Chapter 3 - When does a study require HDEC review?](#)); the whole of the proposal must be submitted for ethical review to an HDEC.

An extension to an existing ethics approval may be sought if proper justification is provided. However, fresh ethics approval must be sought where there has been a significant change to a project. For example, the addition of the collection of blood to a protocol.

The HRC reserves the right to request to review all relevant documents relating to the ethics review of an HRC-funded proposal, including the ethics application, and be satisfied that the research is ethically acceptable in accordance with s31 of the HRC Act 1990.

2.5.1 Application to an approved ethics committee

The first step in obtaining ethics approval for an application for HRC research funding is to submit an application for ethical review to an approved ethics committee.

A research proposal which involves both human and animal subjects will require separate approvals from both human and animal ethics committees.

2.5.2 Locality authorisation

For information on locality authorisation, see the [SOPs Chapter 10](#).

2.5.3 Ethics committee decision

Following review by an ethics committee, the investigator submitting the research proposal for approval will be informed of the outcome of the committees' deliberations. The HRC suggests that the reviewing ethics committee/s respond with one of the following decisions:

- (a) **Approved**, either with or without comments or questions addressed to the applicant; any replies to a committee's comments or questions to be forwarded in due course;
- (b) **Approved subject to conditions**, subject to recommended revisions of the proposal and/or provide satisfactory answers to questions asked of the applicant. The applicant's reply and/or revised proposal must be forwarded via the committee administrator to the chairperson and/or delegated committee members to consider the revisions that have been made and to provide final approval;
- (c) **Approval deferred**, pending substantial revisions of the proposal/study and/or satisfactory answers to questions asked of the applicant. The applicant's reply and/or revised proposal must be forwarded to the committee for reconsideration and final approval; and
- (d) **Approval declined**. Reasons for declining approval to be forwarded to the applicant, either with or without an invitation to submit a substantially revised protocol for reconsideration. As well as giving reasons for declining the application, the ethics committee should provide suggestions for a restructuring of the research project along ethically acceptable lines.

Every decision, comment, or direction of an ethics committee should be made in writing to the principal investigator.

When ethics approval for the research is received by the applicant, the host institution(s) must be given a copy. Evidence of the approval should be included with the funding application or forwarded to the HRC EC administrator as soon as it is received (normally) by the host institution. Where a contract is awarded, evidence of all approvals will be required before the HRC releases funding.

The successful applicant must also inform the host institution about ethics approval of the research.

2.6 Retrospective approval

No retrospective approval for any study shall be given by an approved ethics committee.

2.7 Reviews of decisions by ethics committees

2.7.1 Reconsideration

The researcher, the funder, or where relevant, a participant, may seek a reconsideration of a decision made by an ethics committee from that committee itself.

2.7.2 Review by HRC EC (Second opinion)

Ethics committees, researchers, a funder, or where relevant, a participant, may seek a second opinion from the HRC EC.

For processes of HDECs, see the [SOPs Chapter 9 \(Second opinion on the merits of the decision\)](#).

2.7.3 Appeal

By written notice issued in accordance with section 25(1)(h)(ii) of the Health Research Council Act 1990 on 24 September 2010, the Minister of Health authorised the HRC EC to undertake the additional function of considering appeals against decisions made by the HDECs.

The processes set out in this section are not intended to replace the existing provisions for complaints regarding decisions of committees outlined in the [SOPs Chapter 9 \(Formal complaints about the decision making process\)](#).

- (a) An application for consideration of an appeal may only be made where:
 - i. an approved HDEC has reviewed a proposal and issued a decision in the terms set out in the [SOPs Chapter 7](#), and;
 - ii. attempts have been made in good faith to resolve differences between the applicant and the reviewing HDEC (taking into account, where appropriate, provisions in the [SOPs Chapter 9 \(Formal complaint about the decision-making process and Second opinion on the merits of the decision by HRC EC\)](#), and;
 - iii. subject to paragraph (e) below, a second opinion has been provided under the processes set out in the [SOPs Chapter 9 \(Second opinion on the merits of the decision by HRC EC\)](#).
- (b) Where the conditions in paragraph (a) have been met, the coordinating investigator named on the proposal under consideration may lodge an appeal with the Chair of the HRC EC.
- (c) The appeal must be lodged within 60 days of the date upon which the Chair of the HRC EC is satisfied that the conditions in paragraph (a) are met.
- (d) In exceptional cases upon a specific request from an applicant and following consultation with a quorum of the HRC EC, the Chair of the HRC EC may:

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- i. allow an interested third party to lodge an appeal where the Chair is satisfied that restricting the right to lodge an appeal to the coordinating investigator would be inequitable;
- ii. waive the requirement to obtain a second opinion, so allowing direct recourse to the appeal process, where he or she is satisfied that a binding resolution is urgent or that the second opinion process would be futile.

Decisions under this paragraph will be made within 14 days of receiving an application for appeal subject only to reasonable delays occasioned by, for instance, the need to obtain expert advice or further information from applicants.

- (e) The HRC EC will meet to consider an appeal no later than 6 weeks after the application for appeal has been accepted.
- (f) An application for appeal must include:
 - i. a copy of the original application;
 - ii. written comments by the reviewing HDEC explaining their decision;
 - iii. (subject to paragraph d above) a copy of the Second Opinion and all relevant correspondence; and
 - iv. a description of the specific issues which form the basis of the appeal.
- (g) The HRC EC will have broad discretion to consider information relevant to the matter under appeal. The HRC EC will consider information from both the investigator who submitted the application and the ethics committee who completed the Primary Review and, where appropriate, further submissions made by other relevant parties. The HRC EC may consider other information available at the time the original decision was made, or new information that has come to light since.
- (h) Where the Chair or a quorum of HRC EC members believes there is insufficient expertise on the HRC EC to consider an appeal, the HRC EC will seek additional expert advice. Persons and bodies to be consulted under this provision will be identified by the Chair of the HRC EC in consultation with the HRC EC in order to obtain advice appropriate to the matter under review.
- (i) When considering appeals, the HRC EC is bound by the principles of natural justice and, in particular, must ensure that:
 - i. all processes are open, transparent and fair;
 - ii. the committee is unbiased;
 - iii. all parties to the appeal are:
 - advised of the process to be undertaken;
 - given the opportunity to comment on issues (a reasonable period of time should be given for the parties to respond);
 - kept informed of the progress of the appeal ;
 - advised of the outcome of the review;
 - iv. conflicts of interest are avoided or appropriately managed;
 - v. reasons are given for any decisions or recommendations made.
- (j) Meetings of the HRC EC will be closed to the public.
- (k) Copies of appeal requests and decisions will be available to individuals outside the HRC EC, subject to the provisions of the [Official Information Act 1982](#).

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- (l) Wherever possible, the HRC EC should determine matters by consensus decision. Where a consensus cannot be reached, a decision will be made by the majority vote with the Chair having a casting vote.
- (m) The decision of the HRC EC will be binding. The HRC EC will take one of the following actions:
 - i. uphold the decision of the Primary Ethics Committee; or
 - ii. overturn the decision of the Primary Ethics Committee; and approve, approve with conditions, or decline the ethics application.
- (n) In addition to making a decision, the HRC EC may also give non-binding advice or recommendations clearly indicating which parts are non-binding.
- (o) All decisions of the HRC EC will be communicated to:
 - i. the Appellant;
 - ii. the original reviewing Committee;
 - iii. the Committee which delivered the second opinion, if there was one;
 - iv. the Board of the Health Research Council of New Zealand; and
 - v. the Manager, Ethics Committees, Ministry of Health.
- (p) Once the HRC EC has made and communicated its decision on the appeal, the primary ethics committee providing the original review will resume full administrative responsibilities in relation to the original application, such as receiving annual reports, monitoring adverse events, receiving final reports and the like.
- (q) The HRC EC will provide a report on appeals to the Board of the HRC and the Minister of Health on all appeals.
- (r) The Appeal Summary will contain the following information:
 - i. the membership of the HRC EC;
 - ii. the research title;
 - iii. the name and position of the principal investigator;
 - iv. summary of Primary Review;
 - v. summary of Second Opinion provided by the secondary ethics Committee (unless an expedited appeal); and
 - vi. decision of the HRC EC.

2.8 Complaints

Complaints about research involving human participants can be made, where appropriate, to an approved ethics committee, the HRC EC, the relevant institution/organisation involved in the research, the [Health and Disability Commissioner](#), or the [Privacy Commissioner](#).

2.9 Independent Comment

The HRC EC can provide independent comment on ethical problems that may arise in any aspect of health research. Independent comment may be sought from the HRC EC by any person, or may be provided at the HRC EC's own initiative. Where appropriate, the HRC EC may advise

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relevant parties of the process that will be taken by the HRC EC, seek input from relevant parties, and provide the opportunity for relevant parties to comment.

3. Different forms of research

3.1 Use of a new medicine

Clinical trials that involve use of a new medicine require approval under Section 30 of the Medicines Act 1981. The HRC [Standing Committee on Therapeutic Trials \(SCOTT\)](#) undertakes scientific assessment of applications to conduct trials and makes recommendations to the Director-General of Health on whether or not trials should be approved. The majority of applications reviewed by SCOTT are for clinical trials sponsored by the pharmaceutical industry. The review conducted by SCOTT, if required, is a parallel process to the [ethical review](#) for clinical trials.

For more information on SCOTT, see [Standing Committee on Therapeutic Trials | Health Research Council](#).

3.2 Clinical trials

Randomised controlled therapeutic trials are powerful studies for determining the value of new treatments or reassessing established treatments. However the following conditions must be met:

- (a) When the administration of effective treatment is important for the well-being of the patient, a controlled trial can only be undertaken where there is genuine uncertainty about whether the trial treatment is more effective (or has less risk) than the standard treatment with which it is being compared (referred to as being in a state of ' equipoise').
- (b) In general, random allocation to treatments should be conducted after the patient has given consent to randomisation.
- (c) Arrangements for monitoring the results of the trial and for the occurrence of adverse effects should be made at the outset. Research protocols should include stopping rules. Premature termination of the trial should take place if one treatment has been demonstrated to be superior, or if serious adverse effects occur. Monitoring should generally be undertaken by an independent person or committee. The HRC [Data Monitoring Core Committee](#) (DMCC) would welcome the opportunity to be involved where necessary (see **3.2.1 Health Research Council Data Monitoring Core Committee**).
- (d) Scientific assessment of clinical trials that involve the introduction of nucleic acids, genetically manipulated micro-organisms, or viruses or cells into human participants is undertaken by the GTAC (see **3.2.2 Genetic Technology Advisory Committee**).

Fully informed consent with comprehensive information being available to participants is essential (see **2.1.1 Informed Consent**).

Clinical trials in New Zealand should observe the *Good Clinical Research Practice Guideline (Part 11 of the Guideline on the Regulation of Therapeutic Products in New Zealand)*, the *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)*² and the [Ethical Guidelines for Intervention Studies](#).

Before recruitment into the clinical phase of the research, researchers must register their clinical trials in a publicly accessible register (i.e. [Australian New Zealand Clinical Trials Registry \(ANZCTR\)](#) or equivalent WHO standard register)³. This will promote access to information about all clinical trials in New Zealand.

3.2.1 Health Research Council Data Monitoring Core Committee (DMCC)

The DMCC is established to provide objective, independent monitoring of clinical trials funded by the HRC. The DMCC has two main functions:

- (a) to review the monitoring plans for trials funded by the HRC and provide advice to the HRC on whether the plans meet best international practice;
- (b) to constitute a Trial-Specific Data Monitoring Committee for any trial funded by the HRC where this is appropriate and is requested by the investigators. Trial-Specific Data Monitoring Committees are formed from the DMCC membership, plus additional co-opted members who have expertise specific to the trial.

For more information on monitoring of clinical trials, see [Data Monitoring Core Committee | Health Research Council](#).

3.2.2 Genetic Technology Advisory Committee (GTAC)

Scientific assessment of clinical trials that involve the introduction of nucleic acids, genetically manipulated micro-organisms, or viruses or cells into human participants is undertaken by the GTAC.

GTAC is to review for the purposes of seeking an exemption under Section 30 of the Medicines Act (1981) or as required by an approved ethics committee or the HRC of any of its committees.

For more information on GTAC approval, see [Specific Considerations | Health Research Council](#).

3.3 Observational studies

An observational study is either observational research, or, an audit and related activity. To determine whether an activity is observational research, public health investigations, or any other form of audit or related activity, see *section 2 Ethical Guidelines for Observational Studies*.

² The *CPMP Guideline* is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials that involve human participants. The *CPMP Guideline* aims to provide a unified standard for the European Union, Japan, and the United States, as well as Australia, Canada, the Nordic countries and the World Health Organisation (WHO).

³ "Every research study involving human subjects must be registered in a publicly accessible database before recruitment on the first subject" (Declaration of Helsinki).

More than minimal risk observational research requires ethics committee review (see the [SOPs Chapter 3 - When does a study require HDEC review?](#)).

For further information on which observational studies require review by an ethics committee, see [section 3 Ethical Guidelines for Observational Studies](#).

3.4 Social, community-based, public health or health services interventions

When the focus of a study is a whole community (for example, to test the use of an additive in a community's water supply, or a new form of health care delivery); the individual will not usually have the ability to "opt-out". However, individuals may refuse to submit to questionnaires or blood tests, or other instruments designed to obtain data to evaluate the intervention.

All reasonable means should be used by the investigators to inform the population under study of the aims and intent of the proposed research and all possible advantages or disadvantages which may arise from it. It is normal for the investigators to secure the agreement and co-operation of the national or local body responsible for public health in the population to be studied. Where collective decision making is customary it is also advisable to seek the agreement of the community, usually through its chosen representatives. For consent to participate in the research obtained in hui, consult the [HRC Guidelines for Researchers on Health Research involving Māori](#) and [Te Ara Tika: Guidelines for Māori Research Ethics: A framework for researchers and ethics committee members](#).

Although some community based interventions (e.g. an anti-smoking campaign) that do not involve personal contact between the researcher and the study population may not require ethics approval, the evaluation of such interventions which did involve personal contact with individuals or collection of data from them, will require ethics approval. The community to which the intervention and evaluation is targeted should be informed of the study findings once the study has been completed.

3.5 Surveys of the general population

Some types of research require surveys to be undertaken on "total" populations or on samples of the population selected from public records such as the electoral roll. It is considered that direct approaches (for example, by telephone, postal questionnaire or visit interview) to persons in the general population selected in this way do not require approval by any local health or medical body or individual practitioner.

However, it may be appropriate to inform local health practitioners about the study. Investigators should consult with and, where appropriate, obtain ethics approval from an approved ethics committee for the research to proceed. The right of any person to decline to take part in such a survey, or to withdraw from the survey at any time, must always be respected.

Where approaches involve visiting or telephoning research participants at their home, it is generally desirable that some advance notice be given and field staff must be provided with means of personal identification including a reference telephone number which the participant may call to establish the field worker's legitimacy. In some circumstances it may be appropriate to inform local police and other relevant authorities.

Surveys may, on occasion, involve the physical examination or laboratory investigation of participants. In these circumstances informed consent from each participant must always be

obtained before any examination is undertaken, and each participant must be informed of their right to withdraw without explanation from the research at any time without effect to their current or future health care.

The research participant must be informed of any consequences to them due to their withdrawal from the research. Where clinical examination is involved, advance information about the survey for local practitioners and appropriate authorities is of special importance.

3.6 Collection and use of human materials

Human materials are any organ, tissue, secretion or excretion derived from a human source whether living or dead and including the human foetus, placenta and human gametes.

Legal and cultural aspects which need to be considered will differ according to whether the body parts and tissues come from deceased or living persons, or whether they are body tissues which can be described as "surplus". Regulations and guidelines published in the [Human Tissue Act 2008](#), NZ Standard for Non-therapeutic Use of Human Tissue (NZS 8135:2009) and elsewhere, governing collection, storage and use of human specimens must always be observed. Issues of informed consent and privacy of information will also need to be considered.

As a general rule the collection of human materials and their use in research requires the informed consent of the donor, if living.

If the human materials are to be used for future unspecified research purposes the [Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes](#) should be followed.

If established human embryonic stem cell lines are to be used the [Guidelines for using Cells from Established Human Embryonic Stem Cell Lines for Research](#) should be followed.

For more information, see [Specific Considerations | Health Research Council](#).

3.7 Research involving children

The special vulnerability of children makes consideration of involving them as research participants particularly important. To safeguard their interests, and to protect them from harm, special ethical considerations should be in place for reviewing research involving children. For more information, see [Specific Considerations | Health Research Council](#).

3.8 Research involving personal health information

Research which involves the use of personal health information is required to comply with the [Health Information Privacy Code 1994](#). For more information, see [Specific Considerations | Health Research Council](#).

3.9 Research involving Māori

Respect for the principles of partnership and sharing implicit in the Treaty of Waitangi will be observed by incorporating the following requirements into health research proposals. All issues relating to Māori cultural and ethical values should be discussed with the whanau, hapū or iwi concerned along with matters to do with the key questions and aims of the research. The ownership rights of participants to personal data must be respected.

For research that involves or targets Māori research outcomes or methodologies; the [Te Ara Tika: Guidelines for Māori Research Ethics: A framework for researchers and ethics committee members](#) should be consulted along with the [HRC Guidelines for Researchers on Health Research involving Māori](#).

In the case of research initiated within a whanau, hapu or iwi where the investigators and research participants are members of that group, it may be appropriate for a kaumātua or other person of authority in the group to provide a statement that, in their opinion, the proposed research conforms to Māori cultural and ethical values. The HRC EC may review such research proposals and confirm that this mechanism will constitute adequate ethics approval.

It may also be appropriate for the advice of the HRC Māori Health Committee and other appropriate expert groups to be sought by an ethics committee when reviewing a research proposal.

In the event of issues which cannot be reconciled in discussions between the parties involved, the matter may be referred to the HRC EC and the HRC Māori Health Committee for joint comment.

3.10 International collaborations

Any investigator participating in international collaborative research whose project is funded in full or in part by the HRC will require ethics approval from a New Zealand approved ethics committee for the research. Research conducted overseas having human or animal involvement will also require appropriate ethics approval from an ethics committee (or equivalent body) in the country concerned, where such a body exists.

Any international collaborative research project, whether or not funded by the HRC, which involves investigations in New Zealand or its territories, should be subject to ethical review by an approved ethics committee within New Zealand.

For guidance on ethical research in developing countries, investigators should consult necessary documents in the relevant jurisdictions.

3.11 Research undertaken at an overseas location

Investigators who undertake all or part of an HRC-funded fellowship, scholarship or contract overseas are required to provide evidence of appropriate ethics approval for their research.

3.12 Genetic modification

Genetic modification has been used freely in New Zealand for more than a decade as a research tool for medical purposes and in food ingredients.

In 2000, the Government appointed the Royal Commission on Genetic Modification to inquire into the following matters:

- (a) the strategic options available to enable New Zealand to address, now and in the future, genetic modification, genetically modified organisms, and products; and

- (b) any changes considered desirable to the current legislative, regulatory, policy, or institutional arrangements for addressing, in New Zealand, genetic modification, genetically modified organisms, and products.

The report and recommendations of Royal Commission in 2002 can be downloaded from <http://www.mfe.govt.nz>.

3.13 *In vivo* human gene manipulation proposals

All attempts to introduce deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) into humans must be reviewed by an approved ethics committee.

Somatic cell gene therapy involves the introduction of fragments of DNA or RNA into human somatic (non-reproductive) cells. The aim usually is to improve the health of people with certain grave inherited diseases, or with certain forms of cancer, or some virus infections. DNA or RNA may also be introduced into somatic cells to mark their distribution and fate in particular forms of research on serious diseases.

There may also be other well justified non-therapeutic reasons for introducing DNA or RNA. The development of methods of introducing DNA or RNA into somatic cells is acceptable. The introduction of DNA or RNA into germ (reproductive) cells or fertilised ova is not acceptable at present, because there is insufficient knowledge about the possible consequences, hazards and effects on future generations.

The following particular matters need to be taken into account when protocols for somatic cell gene therapy or research are being considered by an ethics committee.

- (a) The therapy should be attempted at present only in monogenic diseases where the cause is a defect in a single pair of genes, or in cancers. There should be good reason to believe that the therapy may improve clinical outcomes.
- (b) Introduction of DNA or RNA for research reasons should have a sound basis in current knowledge of the biological system involved.

3.14 The choice of diseases for clinical therapy or research

The choice of diseases for clinical therapy or research is critical. For the present, evidence of hazards associated with the treatment can only be estimated and evaluated from experiments on animals. Initial trials in human participants therefore should be limited to –

- (a) Diseases for which there is no effective cure, and which cause a severe burden of suffering. Diseases causing a lesser burden, when account is taken of currently available treatment, should become candidates for somatic cell gene therapy or research only after the risks associated with this therapy have been determined by experience in humans over some years.
- (b) Diseases in which the effects of treatment or research can be measured.
- (c) Patients for whom long-term follow-up is available.

When considering an application for somatic cell gene therapy, or introduction of DNA or RNA for research reasons, the researcher should ensure that the following criteria are met:

- (a) That the research team has the necessary depth and breadth of knowledge of, and experience in, molecular genetics.
- (b) That the purity of the DNA or RNA to be inserted and the methods of handling it during its preparation are in accord with current regulations and official guidelines, particularly if viral vectors are used.
- (c) That the technique of insertion has been shown by experiments in animals or cell cultures to:
 - i. confirm the inserted DNA or RNA to the targeted somatic cells; and
 - ii. achieve the intended function in a high proportion of attempts, and
 - iii. rarely cause undesirable side effects.
- (d) That the probability of entry of the DNA into germ cells has been evaluated.

In developing each protocol for somatic cell gene therapy or other uses of human genetic material there must be appropriate consultation with any relevant ethnic group affected by the application, paying particular attention to issues of cultural sensitivity. Specific advice on these aspects should be obtained from the HRC Māori Health Committee.

For any application for research on gene therapy, or introduction of fragments of DNA or RNA for research reasons, the researcher must consult the official national body concerned with monitoring the safety of innovative human genetic manipulation techniques. The relevant New Zealand body is the HRC Genetic Technology Advisory Committee.

3.15 Research involving use of placebos

Applicants should consult the [Declaration of Helsinki](#) on research involving use of placebos. Ethics committees should decide on the circumstances of each case, having regard to all relevant ethical considerations, as to whether approval is to be given for a placebo arm in a randomized control trial.

The World Medical Association affirmed that “*the benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention(s)*”, except in the following circumstances:

- (a) *Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or*
- (b) *Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention, and*
- (c) *the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.*
- (d) *Extreme care be taken to avoid abuse of this option.*

See also: [Ethical guidelines for intervention studies](#) sections 5.22 – 5.25 *Use of a placebo.*

3.16 Research involving animals or animal materials

The HRC requires all research involving animals or animal materials to be submitted for approval by the animal ethics committee of the institution/organisation with which the investigator is associated. Evidence of approval from an animal ethics committee must be documented before funding commences.

If the institution/organisation has no animal ethics committee, guidance on how to set up one for accreditation can be obtained from the [National Animal Ethics Advisory Committee](#) (NAEAC). Alternatively, it is possible to obtain approval to conduct the study under the approval and supervision of an animal ethics committee in the vicinity of the institution/organisation. Guidance can be obtained from the Secretary of [NAEAC](#).

4. General legal issues in research

The following sets out general issues that may have legal relevance. The information provided below is not to be taken as legal advice but as an indication of matters which should be taken into consideration.

4.1 Intellectual property rights

Intellectual Property (IP) results from creative thought, and can include any novel result, idea, device, software, chemical, vaccine, mono-clonal antibody, plasmid, hybridoma, diagnostic method or process.

It is important for researchers to protect their IP by patenting new discoveries or processes and not signing away their UP rights in Materials Use Agreements or collaborative research agreements.

The HRC has IP agreements with the majority of host institutions which it funds.

These agreements assign the HRC's share of any financial benefits from IP developed by an HRC-funded researcher to the institution to support the researcher's group or other public good health research.

4.2 Copyright

Copyright is automatic under New Zealand law without application to any particular body for the legal right to copyright original material. Copyright exists from the time of production of the original copyrighted material. Materials covered by copyright include but are not limited to: written, typed or printed information on any medium, artworks, computer source code and object code, data or results of investigations.

The HRC EC expects that copyright will be respected by investigators and other persons and that New Zealand and international laws relating to copyright will be adhered to in all cases.

4.3 Conflict of interest

To achieve impartiality, any member of an ethics committee who has a proposal before the committee or who has a conflict of interest whereby the impartiality of that member could be questioned, will declare and withdraw at the determination of the committee.

Where an issue arises in relation to a research proposal such that an investigator may have a conflict of interest (whether perceived, potential, or actual), the issue must be referred to an ethics committee for appropriate comment. The primary ethical concern is that any conflict of interest, particularly a financial conflict of interest, may compromise the well-being of research participants. An investigator should disclose any relevant matters that could give rise to a conflict of interest and, where appropriate in the circumstances, the conflict of interest must be avoided or managed. The disclosure and, where appropriate, management of any conflict of interest should be stated in information sheets provided to participants. A review and audit of compliance with policies and processes relating to conflict of interest should be undertaken to identify areas that could be improved.

4.4 Scientific misconduct

Individual host institutions should ensure that there are appropriate guidelines for the conduct of research and procedures for dealing with allegations of misconduct in research.

4.5 Compensation for injuries suffered by participants in research

The [Accident Compensation Act 2001](#) provides cover for treatment injuries caused as part of a clinical trial where an approved ethics committee has approved the trial and is satisfied that the trial was not to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialed.

Treatment injuries are adverse medical events that must be causally linked to the treatment (but do not require a finding of fault) and are not a necessary part or ordinary consequence of the treatment.

The World Health Organisation defines a clinical trial as:

“Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.”

In order to ensure that there is cover under the Accident Compensation Act it is important that the trial is submitted to an approved ethics committee for approval, and that the researcher indicates to the effect that the study will not be carried out principally for the benefit of the manufacturer or distributor of the medicine or item in question. If approval is not granted by an approved ethics committee, the trial may not commence or proceed.

Any agreement in writing from a person who will participate in a trial should include all the requirements necessary to enable that person to give his or her fully informed consent, including information on compensation cover.

A claim for cover under the Accident Compensation Act is a matter for decision by ACC. In the circumstances where a claimant has cover and is eligible for the entitlement, the claimant's entitlement will depend on a number of factors, such as whether the claimant is an earner or non-earner.

4.6 Civil liability

Where personal injury results from negligence during a non-approved clinical trial, or a clinical trial conducted by a manufacturer or distributor principally for the purpose of testing or proving a product, the injured person will have a right to sue for common law damages.

In respect of a trial that is conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialed, it will be necessary for the researcher to ensure that all parties (including the researcher, the manufacturer, the distributor and the host institution) are adequately insured to meet any potential liabilities. Failure to ensure that all parties have adequate insurance will make the research unethical.

For research that is not eligible for cover under the Accident Compensation Act 2001, researchers must ensure that participants and the approving ethics committee are provided with evidence of adequate insurance cover in the event of injury resulting from participation in the research study.

The Researched Medicines Industry Association of New Zealand (RMI) has published [Guidelines on clinical trials compensation for injury resulting from participation in an industry-sponsored clinical trial](#).

Researchers should note that insurance cover does not provide protection from civil liability unless the terms of the policy provide cover against such liability.

4.7 Practicing certificates for ethics committee members

[The Health Practitioners Competence Assurance Act 2003](#) provides a framework for the regulation of health practitioners in order to protect the public where there is a risk of harm from professional practice.

The Medical Council of New Zealand (Council) registers doctors to practices in New Zealand. The Council has indicated that any medically qualified person has to have an Annual Practicing Certificate if they are to engage in any activities which potentially could impact on public health and safety. An exemption can be sought from the Council for medical professionals who have retired.

As medically qualified ethics committee members are appointed for the purpose of their professional knowledge and experience, it is the view of the HRC EC that a medical practitioner should hold a current Annual Practicing Certificate or an exemption.