November 2012

HRC Guidelines for Approval of Ethics Committees (*Approval Guidelines*)

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1. Introduction

The Health Research Council Ethics Committee (HRC EC) is established under the Health Research Council Act (1990) as a committee of the Health Research Council (HRC). Section 25 covers the functions of the HRC EC. Set out below are the functions relevant to the approval of ethics committees:

25(1)(c) 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;

and,

25(1)(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.

The number of applications received for funding consideration by the HRC means that the HRC EC is unable to review these itself. The requirement for independent ethical assessment also provides a reason for the HRC EC to delegate its approval functions under the Act. Consequently, the HRC EC approves ethics committees pursuant to the final phrase of section 25(1)(c).

The HRC EC 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. In considering approval of such ethics committees, the HRC EC is acting in accordance with section 25(1)(f) of the HRC Act 1990.

To ensure that appropriate standards are met, the HRC EC has developed these guidelines for ethics committees and their governing bodies setting out the requirements of HRC EC for gaining approval. They include the requirements for approval, annual reporting and re-approval. The HRC EC requires this information to satisfy itself that the on-going delegation of its functions regarding independent ethical assessment is appropriate.

2. Types of human ethics committees

There are two types of human ethics committee. The distinction between these is based upon their lines of reporting and responsibility. These are:

2.1 Health and Disability Ethics Committees (HDECs)

HDECs are established as Ministerial Committees under section 11 of the New Zealand Public Health and Disability Act 2000. 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 contained in the Ethical Guidelines for Observational Studies and Ethical Guidelines for Intervention Studies. They have their own standard operating procedures (the SOPs) that define the role and review process of HDECs, as well as provide rules and guidance on the health and disability research that they review.

2.2 Institutional Ethics Committees (IECs)

IECs are established by organisations that include tertiary educational institutions, private sector organisations, and public sector organisations, except the HDECs. IECs comprise all research ethics committees which report to the central or governing body of an organisation (as opposed to reporting to, for example, a department of the organisation). Most research that IECs review is not health related. Each IEC has its own policies and procedures that reflect the nature of the research that it reviews. Insofar as their work is not directly HRC related, the HRC EC approves these committees pursuant to section 25(1)(f) of the HRC Act.

3. Why obtain HRC EC approval

The HRC EC has responsibility to approve all human ethics committees which provide independent ethical assessment for HRC funded research. In addition to seeking approval so that the committee may review HRC funded research, ethics committees may seek HRC EC approval for the following purposes:

3.1 Accident Compensation Act 2001 - The Act provides coverage for participants in a clinical trial who sustain treatment injury where an ethics committee approved the trial and was satisfied that the trial was not to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. The ethics committee providing such approval must be approved by the Health Research Council of New Zealand or the Director General of Health (section 32(6)).

3.2 The use of the New Zealand Health Information Service database (NZHIS) - The policies governing access to the data held by the NZHIS allow for disclosure of information for research purposes only if the research protocol has been approved by an ethics committee approved by the Health Research Council or the Director General of Health and the information will not be published in a form which could reasonably be expected to identify the individual concerned. The release of information is also subject to the provisions of the Privacy Act 1993 and the Health Information Privacy Code 1994.

3.3 All research involving the use of health information other than that held in the New Zealand Health Information Service database must comply with the provisions of the Privacy Act 1993 and Health Information Privacy Code 1994. Rule 11 (2) (c) (iii) of the Code enables health information to be used for research purposes (for which approval by an ethics committee, if required, has been given).

3.4 Approval by HRC EC provides recognition that the ethics committee is functioning according to internationally set standards.

4. Requirements for approval

To grant approval for an ethics committee, the HRC EC needs to be satisfied that the ethics committee is able to offer sufficient protection to the research participants and can maintain the reputation of ethical review in general.

Application for approval should be made to the HRC EC who will consider the application at its next available meeting. Meetings are held four times a year around February, May, August and November.

Approval will never be granted retrospectively.

Application for approval should provide information on committee membership, policies and procedures, how the committee will ensure responsiveness to Māori of the research it considers, and the ethical standards against which it will assess research proposals.

4.1 Formal request for approval

The organisation that sets up the ethics committee must formally request approval.

4.2 Membership

a) Guiding principle

The primary guiding principle for appointing members to the ethics committee is to ensure that the committee has the appropriate expertise, skills, knowledge and perspectives to conduct ethical review of the best quality.

Membership should be capable of ensuring a review which is robust, expert, and includes an element of independence.

Members should possess an attitude that is accepting of the values of other professions and community perspectives, and it is important for committees to be comprised of people from a range of backgrounds, expertise and ethnicities.

Despite being drawn from groups identified with particular interests or responsibilities in connection with health and community issues, appointed members are not in any way the representatives of those groups. They are appointed in their own right to participate in the work of the committee as equal individuals of sound judgement, relevant experience and adequate training in ethical review.

b) Lay/non-lay membership

The ethics committee should have a lay Chairperson and a non-lay Deputy Chairperson.

A layperson is a person who:

- has no affiliation to the institution that sponsors, funds, or conducts research reviewed by that committee, and
- is not a registered health practitioner, and has not been a registered health practitioner at any time during the five years preceding in the date of their appointment, and
- is not involved in conducting health or disability research, or employed by an organisation whose primary purpose relates to health and disability research, and
- may not otherwise be construed by virtue of employment, profession, relationship or otherwise to have a potential conflict or bias with the work of the committee.

c) Composition of ethics committee

The membership requirements must be "fit for purpose" and set out in the Terms of Reference of the committee.

Membership must reflect the knowledge and expertise that an ethics committee requires to ensure (1) protection of research participants, and (2) the enhancement of public confidence in the system of ethics review.

An ethics committee should take the following factors into consideration when appointing members.

i) Committees must be large enough to ensure that a range of perspectives, experience and expertise are represented in the ethical review. Where relevant to the committee's scope of work, members should include individuals with experience and expertise in:
   - a recognised awareness of te reo Māori and the understanding of tikanga Māori,
   - ethical and moral reasoning,
   - law,
   - the perspectives of wider community (e.g. the perspectives of consumers of health and disability services, ethnic community)
   - the design and conduct of intervention studies,
   - the design and conduct of observational studies,
   - the provision of health and disability services,
   - reviewing either qualitative or quantitative research,
   - the perspectives of student community.

   It is important to note that a person could fall into more than one of the above categories.

ii) The quorum for any meeting must be at least half of the appointed members (including the chairperson or acting chairperson).

iii) An ethics committee that reviews health research must appoint sufficient members whose background is not in health research to ensure that they feel comfortable voicing their views.

iv) For ethics committees that review low risk health research, the HRC EC requires two appropriately qualified health professionals, one clinically trained and one in active practice.

v) Gender balance of an ethics committee should be as close to half male and half female as practicable.

vi) In some situations a conflict may arise in terms of appointment of new or replacement members where it is not possible to comply exactly with the requirements of the *Approval Guidelines*. An example of such a situation would be where both a member with science expertise and a Māori member need to be appointed and the appointment of a lay member would unbalance committee membership. The HRC EC expects that as a general principle, the appointment of the Māori member will take precedence over other considerations of balance. The lay/non-lay and gender balance of the committee will be taken as secondary issues in this instance. The order of priority is - Māori, gender, lay versus non-lay, other cultural considerations.

d) Documents required

The HRC EC requires a list of members of the committee indicating:

i) the status of each member of the committee as lay or non-lay ;
ii) the areas of expertise or experience which each member brings to the committee (e.g. ethics, law, Tikanga Māori, qualitative research, quantitative research, community involvement (state wider, Māori or student community), medical practice, health research);
iii) the gender of each appointed member;
iv) the membership start and finish date of each appointee;
v) how the member was appointed (e.g. public nomination and interview by committee member(s), nomination by a professional body (state which), nomination by institution); and
vi) a short biography for each member.

4.3 Policies and procedures

The organisation that sets up the ethics committee has the responsibility to establish the necessary policies to govern the ethics committee. To ensure efficient operation, the policies and written procedures adopted by the ethics committee should be reviewed periodically as part of an ongoing assessment of performances and outcomes, to determine whether any revisions are needed.

Through the process of approval, the HRC EC will review the policies and procedures of the ethics committee and may suggest revisions if necessary for the ethics committee to be approved.

The policies and written procedures must include the following topics:

a) Terms and conditions of appointment

The HRC EC takes the view that a systematic turnover of members is important for the effective functioning of an ethics committee over time. The terms of office of members shall be staggered to ensure continuity of membership.

HRC EC recommends that members of an ethics committee be appointed for up to three years, with reappointment to a maximum of six years in total, and that three years should elapse before a further term of appointment. However, the HRC EC is aware that there may be practical difficulties in recruiting members in some categories, and of the value of experienced members of the committee, and so the HRC EC will consider an extension of an appointment beyond six years where the effectiveness of the committee would otherwise be compromised.

b) Training

The HRC EC expects an ethics committee to provide appropriate training for new members and on-going training for its existing members throughout the terms of office.

c) Chairperson

The committee should be chaired by a lay person with no primary background in health research or with no affiliation to the institution or organisation that is responsible for the committee. The chair needs to have established skills in consensus decision-making.

If it is not possible or feasible to appoint a lay person as the chairperson of an ethics committee, the situation should be managed appropriately with a comment in the annual report detailing the processes the committee adopts for dealing with perceived, potential or actual conflicts of interest.

d) Review processes

The HRC EC has a preference for ethics committees to meet face-to-face because it believes that such interaction best ensures robust and thorough review. However, other means of review will be considered for approval. The HRC EC recognises that ethics committees may adopt a range of review processes, such as:

i) all applications reviewed by committee members by email and only those with queries discussed at face-to-face committee meetings;
ii) some applications reviewed by subcommittees of the approved ethics committee, and
iii) low risk applications reviewed by departments/schools with a list sent to the approved ethics committee.

For approval, the HRC EC must be satisfied that the process ensures robust ethical review. The ethics committee will need to provide convincing evidence that this is the case.

e) Decision making process

The HRC EC prefers consensus decision-making wherever possible, because it believes it is more likely to reflect the full range of views on the committee. Consensus does not require that all members support the decision, but that all members consider the decision acceptable. In order for an ethics committee to be able to function with a consensus decision making approach members of committees must be free to participate fully in discussion and debate. It is particularly the role of the Chair to ensure this happens.

On occasion, individual members may wish to abstain from some or all of the decision making process because of strong personal, moral or religious reasons. Such abstentions shall not affect the approval process.

Other methods of decision making are possible (such as voting by a simple majority of members present with the chair having a casting vote) but these need to be justified and pre-defined for approval.

f) Consultation outside the committee

The HRC EC encourages committees to have members with a range of relevant expertise, experience and understanding, but recognises that on occasion a committee may feel the need to consult outside their regular membership. This consultation may be either on ethical or on more technical issues. For example, on ethical issues this may be with individuals, groups, iwi and hapu. The HRC EC supports and encourages such consultation. However, the confidentiality of the proposal and details of the issue under appraisal must be protected.

Where there is insufficient expertise on the committee to assess an application properly or address an issue raised, the ethics committee should seek additional expert advice. Such experts may be invited to attend a relevant meeting to provide advice, but they should not be present during committee deliberations.

g) Other processes

To be approved, an ethics committee will need to detail any variations to normal processes of review, for example, fast-track (expedited) review, variations for particular protocols (e.g. student research projects, key informant interviews), chair's action, and so on.

The HRC EC will need to be satisfied that a complaints procedure for the research participants, researchers and other interested parties is in place.

In relation to research involving Māori, it is important that Māori expertise be available to ensure that all issues are appropriately considered. Where it is not

possible for Māori members to attend a meeting or for those members' views to be sought and represented at the meeting, the matter should be deferred.

h) Documents required

The HRC EC requires a complete set of policies and procedures outlining:

i) the functions of the committee;
ii) the Terms of Reference of the committee
iii) the decision making process;
iv) the process for ensuring there has been appropriate peer review of the research proposal;
v) the method of submitting and reviewing application;
vi) the kind of applications which require ethical approval;
vii) the details of research activities for which ethical approval would not be required;
viii) the descriptions of normal procedures for review;
ix) the descriptions of any variations to the normal procedures and the types of research protocols that can be reviewed under these variations (e.g. review under departmental level, by delegated or subcommittee; expedited review; low risk review);
x) the details of the complaints procedure;
xi) the details of the lines of reporting and responsibility to and from the ethics committee, in respect of its parent body and any sub-committees (inclusion of a structure diagram is encouraged).

4.4 Responsiveness to Māori

In order for approval to be considered, committees must provide a brief profile of the strategy of the policy in ensuring Treaty and Māori responsiveness. This may include the policy of the organisation on Treaty and Māori responsiveness relative to the core activity of the committee or the strategic policies specific to the committee including how consultation with Māori is facilitated.

Committees are requested to highlight how they implement the relationship in terms of informal input, shared decision-making, recruitment of members and support mechanisms given to ensure all committee members share the responsibility of working towards improving Māori outcomes and reducing inequities for Māori, thus giving value to the principle provisions of the Treaty of Waitangi.

4.5 Ethical standards

The HRC EC needs to be reassured that ethics committees seeking approval are applying nationally/internationally accepted standards for the conduct of research. These may include: scientific design and conduct of the study, informed consent, risks and potential benefits, selection of study population and recruitment of research participants, payments for participation in research, protection of research participants' privacy and confidentiality, and cultural sensitivity. The HRC EC would

expect these standards to be set out in the policies and procedures on research under which the ethics committee operates. All national and international guidelines to which the organisation adheres should be referenced (for example, the Ethical Guidelines for Observational Studies, the Ethical Guidelines for Intervention Studies, the Code of Health and Disability Services Consumers' Rights, the Health Information Privacy Code).

Documents required

The HRC EC requires an indication of the guidelines which the ethics committee applies and copies of the policies, such as:

i) informed consent procedures, including those which meet the requirements of the Code of Health and Disability Services Consumer's Rights where the research relates to patients;
ii) policy relating to minimisation of risk of harm;
iii) policy relating to compensation for injury or harm to participants;
iv) policy for payments for participants in research;
v) policy on protection of research participants' privacy and confidentiality;
vi) policy on response to cultural sensitivity, including the policy of the organisation on Treaty and Māori responsiveness relative to the core activity of the committee or the strategic policies specific to the committee including how consultation with Māori is facilitated.

5. Duration of approval, dates for annual reporting and re-approval

Approval is for a maximum term of three calendar years, subject to satisfactory review by the HRC EC of the annual reports of the approved ethics committee.

Annual reports are due by three months after each anniversary of the approval. For the requirements of the annual report, refer to **section 6: Requirements for annual reporting**.

Re-approval applications have to be submitted at the same time the annual report is due in the final year of approval. For the requirements for re-approval, refer to **section 7: Requirements for re-approval**.

6. Requirements for annual reporting

Approval may be given for an ethics committee for three calendar years. During the approval period an ethics committee is required to provide an annual report to the HRC EC for review, in order to maintain the approved status.

Annual reporting includes reports on matters of: administration, appointments, workload, any other aspects of the operation of committees deemed to be significant, and substantive matters of ethical concern.

The HRC EC will review the documentation provided and provide an outcome on this review for continued approval following the HRC EC meeting which receives the report.

Requirements for the annual report

An ethics committee should submit the *Annual report form for an ethics committee* (available from the HRC website www.hrc.govt.nz) by the due date.

Annual reports are required by the HRC EC three months after each anniversary of the approval for consideration at the next available meeting of the HRC EC.

The annual report must include the following:

i) The Chairperson's report that summarises the main progress, changes and any issues from the last reporting year. This may include (but not limited to) –

- workload
- resources
- changes to committee policies
- changes to structure of review (e.g. introduction of low risk expedited review)
- institutional climate (e.g. undergoing restructure)
- scenarios of difficult review, areas of review that caused difficulty for the EC in making a decision on any particular protocol(s)
- requests for advice on how to review particular topics, any other substantive changes which the committee or its Chair feels should be noted
- any questions on policy or other matters which the EC wish to put to the HRC EC for comment or guidance

ii) A summary of any changes in the policies and procedures which the ethics committee applies.

iii) The composition of the ethics committee, including –

- Summary of experience and expertise of members.
- Status of chairperson and deputy chairperson.
- The number of members in the core membership categories.

iv) Details of the membership of the ethics committee, including –

- List of members with commencement and end of term dates. It is also preferred that the iwi of Māori members are noted.
- A short biography for each member.
- A list of all retirements/resignations and new appointments of members.
- A schedule of the attendance of individual members at meetings with an explanation of absences if appropriate.

v) Details of the training, including the attendance of each session, used to orient new members, and ongoing training for committee members.

vi) Details of the operations of the ethics committee, including –

- Assessment time of ethics approvals.
- Number of delegated decisions.
- Details of second opinions sought/provided.
- Details of complaints received.
- A summary of the total numbers of applications received, subdivided into the outcome areas.
- Explanatory comments on declined proposals and transfer to an HDEC.
- Issues with regards to Māori consultation.

vii) Details of the protocols considered by the ethics committee, including –

- Protocol reference number
- Protocol title
- Name of principal investigator
- Date of receiving the application
- Date of first review
- Outcome of first review
- Status at time of report
- Date of final outcome
- Locality
- Funder
- Consultation undertaken

In compiling the reports, committees should take care to not provide information which would involve a breach of the Privacy Act 1994 and/or the Health Information Privacy Code 1994.

7. Requirements for re-approval

Applications for re-approval must be made at the same time the annual report is due. The HRC EC undertakes to review all applications in time to ensure that there is no period when the ethics committee is not approved, providing it meets the required standards.

The ethics committee does not need to complete a separate annual report form when seeking re-approval. Instead, the ethics committee is required to submit the *Report from an ethics committee seeking re-approval* (RA). This form includes the annual report for the preceding year and the re-approval summary report. The RA is available on the HRC website www.hrc.govt.nz .

Other than the information required for annual reporting (see **Section 6**), the RA must include the following information in the re-approval summary report:

i) A Chairperson's report that provides a summary of the performance of the committee over the last 3 years. The main issues faced by the ethics committee, any important trends in the overall functioning and the achievements of the ethics committee within the approval period.

ii) A brief comment on the changes in policies and procedures over the last 3 years and how the changes have positively or negatively affected the ethics committee in terms of its stability and functioning.

iii) Details of policies and procedures. For information required, see **section 5.3.**

iv) Identify the gaps within membership expertise over the last 3 years and explain the initiatives that have been implemented to address these issues.

v) A brief comment on the annual turnover of membership over the last 3 years and their effects (both positively and negatively) on the ethics committee.

vi) The strategies that had been used in inducting new members and developing the expertise of committee members over the last 3 years.

vii) The reporting mechanism that has been established between the ethics committee and the organisation responsible for it.

viii) The application review process.

ix) A comment on the effectiveness of the application review process over the last 3 years and the initiatives that had been implemented, or planned, to enhance the process.

x) The issues with reaching quorum and how these issues are resolved.

xi) The process the ethics committee used to ascertain feedback from stakeholders.

xii) A description of the process for researchers whose application for ethical review is deferred or approved subject to conditions (or equivalent).

xiii) Details of Chairperson's delegation.

xiv) A brief profile of the ethics committee's policy in ensuring Treaty and Māori responsiveness. See **section 5.4** for more details.

xv) A description of how the ethics committee has ensured that researchers have sought appropriate Māori consultation.

xvi) The arrangements that are made for proposals involving ethnic communities.

If necessary the HRC EC may request additional information or comment from the ethics committee or its Chair.

In special circumstances, the HRC EC may agree to provide a short extension to the current period of approval if it is clear that this extension will allow the committee seeking re-approval to submit the required information.

A formal request for an extension period must be submitted by the Chair of the ethics committee. The request must include the reasons for the extension. An example of a situation where an extension may be justified is where the ethics committee itself is under review by its parent organisation and the result of this review is not known in time for the submission of the annual report and request for re-approval.

If successful, re-approval will be given for a further three year term, subject to the ongoing satisfactory review of the annual report of the ethics committee.

Re-approval will never be granted retrospectively.

8. Failure to seeking re-approval

Failure to seeking re-approval will mean that the approval status of the ethics committee will lapse at the end of the current approval period.

An ethics committee which is not approved is not able to review applications relating to: (i) HRC funding, (ii) accident compensation cover for clinical trials or (iii) the use of health information, including access to the NZHIS databases.

9. Failure to maintain appropriate standards

Failure to maintain the appropriate standards for continuity of approval will mean that approval will either be suspended until issues have been satisfactorily addressed or withdrawn.

An ethics committee which has had their approval suspended or withdrawn is not able to review applications relating to: (i) HRC funding, (ii) accident compensation cover for clinical trials or (iii) the use of health information, including access to the NZHIS databases.

10. Enquiries

Enquiries concerning approval, annual reporting and re-approval should be directed, in the first instance, to:

The Secretary
HRC EC
Health Research Council of New Zealand
P O Box 5541, Wellesley Street, Auckland 1141

Ph: 09 303 5221
Fax: 09 377 9988
Email: ethics@hrc.govt.nz

11. References to guidelines, legislation, regulations and codes

i) HRC guidelines

- HRC Guidelines on Ethics in Health Research (2005) (currently under review)
- Guidelines for Researchers on Health Research Involving Māori (2010)

ii) Other guidelines

- Ethical Guidelines for Observational Studies (National Ethics Advisory Committee, 2012)
- Ethical Guidelines for Intervention Studies (National Ethics Advisory Committee, 2012)
- Guideline on the regulation of therapeutic products in New Zealand Part 11: Good clinical research practice and obtaining approval for clinical trial (Ministry of Health, 2011)
- Standards and operational guidance for ethics review of health-related research with human participants (World Health Organisation, 2011)
- Standard operating procedures for Health and Disability Ethics Committees (Ministry of Health, 2012)

iii) Legislation

- Accident Compensation Act 2001
- Health Research Council Act 1990
- Human Rights Act 1993
- Official Information Act 1982
- Privacy Act 1993
- Public Records Act 2005

iv) Regulations

- Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996
- Health (Retention of Health Information) Regulations 1996

v) Codes

- Health Information Privacy Code 1994