The Health Research Council of New Zealand

HRC Guidelines for Ethics Committee Accreditation

June 2008
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Amended June 2008
1. Introduction

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

- 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:

- 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 and the requirement for independent ethical assessment mean that the HRC Ethics Committee is unable to provide the resources necessary to complete this task itself. Therefore, the HRC Ethics Committee needs to delegate this responsibility.

To ensure that appropriate standards are met, the HRC Ethics Committee has developed these Guidelines for ethics committees and their governing bodies setting out HRC Ethics Committee’s requirements for gaining accreditation. They include the generic and specific requirements for accreditation and reaccreditation including annual reporting requirements and details of the committee’s membership and procedures. The HRC Ethics Committee requires this information to satisfy itself that the on-going delegation of its functions regarding on-going independent ethical assessment is appropriate.

Accredited ethics committees are able to undertake independent assessment on behalf of the HRC Ethics Committee.

2. Types of Ethics Committees

The HRC Ethics Committee has responsibility to approve all human ethics committees which provide independent ethical assessment of HRC funded research. There are two types of human ethics committee. These are:

- Health and Disability Ethics Committees (HDECs)
- Institutional Ethics Committees (IECs)

The distinction between these is based upon their lines of reporting and responsibility.
Seven HDECs (six regional and one multi-region) were established as Ministerial Committees under section 11 of the New Zealand Public Health and Disability Act 2000. The terms of reference set out details of the composition of the committee and the procedures they need to follow.

IECs comprise all other 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). IECs include committees from tertiary educational institutions, private sector organisations, and public sector organisations except the HDECs.

A list of accredited human ethics committees is available from the HRC website www.hrc.govt.nz.

3. Why Obtain HRC Ethics Committee Accreditation

In addition to seeking accreditation so that the committee may review HRC funded research, ethics committees may seek HRC Ethics Committee accreditation for the following purposes:

i)  The Injury Prevention, Rehabilitation and Compensation Act 2001 (IPRAC Act) - The Act provides coverage of 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 HRC Ethics Committee or the Director General of Health.

ii) The use of the New Zealand Health Information Service database - 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 accredited by the HRC Ethics Committee or the Director General of Health. The release of information is also subject to the provisions of the Privacy Act 1993 and the Health Information Privacy Code 1994.

iii) 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) enables health information to be used for research purposes (for which approval by an ethics committee, if required, has been given).

iv) Accreditation provides recognition that the ethics committee is meeting standards based on internationally set standards.
4. **How to Obtain Ethics Committee Accreditation**

The first step for an ethics committee seeking accreditation from the HRC Ethics Committee or organisations wanting to establish an accredited ethics committee is to review the Ministry of Health’s *Operational Standard for Ethics Committees* (Ministry of Health, March 2002, updated April 2006).

While the *Operational Standard for Ethics Committees* is written with health research in mind, the principles of ethical review apply to all research.

The following appendices to these Guideline set out the specific requirements to achieve accreditation for the two different types of ethics committees:

Appendix 1  Health and Disability Ethics Committees (HDECs)  
Appendix 2  Institutional Ethics Committees (IECs)

Applications for accreditation should be made to the HRC Ethics Committee and include the information requested in the appropriate section. Applications are considered at the next meeting of the HRC Ethics Committee. Meetings are held four times a year in February, May, August and October.

5. **Duration of Accreditation and Dates for Annual Reporting**

Accreditation is for a maximum term of three calendar years from the date of notification by the HRC Ethics Committee until 30 June in the third year for committees with a 31 December year end, or 31 December in the third year for committees with a 30 June year end, subject to satisfactory review by the HRC Ethics Committee of the accredited ethics committee’s annual reports.

Annual reports are due by 1 April each year for committees with a 31 December year end and by 15 September for committees with a 30 June year end. For the content of the Annual Report, refer to Appendix 1 for HDECs and Appendix 2 for IECs.

<table>
<thead>
<tr>
<th>COMMITTEE’S YEAR END</th>
<th>ACCREDITATION END DATE</th>
<th>ANNUAL REPORT DUE</th>
<th>REACCREDITATION DUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>31 December</td>
<td>30 June (in third year of accreditation)</td>
<td>1 April</td>
<td>1 April in the final year of accreditation</td>
</tr>
<tr>
<td>30 June</td>
<td>31 December (in third year of accreditation)</td>
<td>15 September</td>
<td>15 September in the final year of accreditation</td>
</tr>
</tbody>
</table>

*Please note these new dates:* They bring the dates for Annual Reporting and applications for Reaccreditation into line.
6. **Procedures for Reaccreditation**

Applications for reaccreditation should be made by 1 April in the final year of accreditation for committees with a 31 December year end, or 15 September in the final year of accreditation for committees with a 30 June year end. The HRC Ethics Committee undertakes to review all applications in time to ensure that there is no period when the ethics committee is not accredited, providing it meets the required standards.

The procedure for reaccreditation at the end of the three year term is similar to the process for accreditation (refer to Appendix 1 for HDECs and Appendix 2 for IECs). The ethics committee submits the relevant documentation as if seeking accreditation for the first time. The material is reviewed by the HRC Ethics Committee and the outcome sent to the ethics committee. If necessary the HRC Ethics Committee may request additional information or comment from the ethics committee or its Chair.

In special circumstances, the HRC Ethics Committee may agree to provide a short extension to the current period of accreditation if it is clear that this extension will allow the committee seeking reaccreditation 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 reaccreditation.

If successful, reaccreditation will be given for a further three year term, subject to the ongoing satisfactory review of the committee’s annual report.

Accreditation will never be granted retrospectively.

7. **Failure to Renew Accreditation**

Failure to renew accreditation will mean that the accredited status of the ethics committee will lapse at the end of the current accreditation period.

An ethics committee which is not accredited 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.

8. **Failure to Maintain Appropriate Standards**
Failure to maintain the appropriate standards for continuity of accreditation will mean that accreditation will either be suspended until issues have been satisfactorily addressed or withdrawn.

An ethics committee which has had their accreditation 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.

9. Enquiries

Enquiries concerning accreditation should be directed, in the first instance, to:
The Secretary
HRC Ethics Committee
Health Research Council of New Zealand
P O Box 5541, Wellesley Street, Auckland

Ph: 09 303 5216
Fax: 09 377 9988
Email: ethics@hrc.govt.nz
Appendix 1

Accreditation for Health and Disability Ethics Committees

Regional and Multi-Regional Health and Disability Ethics Committees (HDECs) are established as Ministerial committees under section 11 of the New Zealand Public Health and Disability Act 2000. The Operational Standard for Ethics Committees (Operational Standard) applies to ethics committees that review the ethics of research and innovative practice, and provide advice on issues relating to the delivery of health and disability services. The Operational Standard derives its public authority from the terms of reference of ethics committees established by the Minister of Health under section 11 of the New Zealand Public Health and Disability Act 2000. Those terms of reference have precedence over the Operational Standard on any point of conflict.

This Appendix considers:

- Composition and membership
- Terms and conditions of appointment
- Chairperson and Deputy Chairperson
- Decision making process
- Applications for Accreditation and reaccreditation processes
- Annual Reporting (for continued accreditation)

The HRC Ethics Committee accredits HDECs according to the criteria described below. Sections 1 to 4 are extracts from the Terms of Reference for HDECs. For these sections, requirements from the HRC Ethics Committee are noted in italics.

1. **Composition and Membership**

   **Guiding principle**

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

   **Member numbers**

   The number of members should be 12.

   **Lay/Non-lay membership**

   One half of the total membership shall be lay members, including a lay Chairperson and a non-lay Deputy Chairperson. A lay person is a person who is not:
• currently, nor has recently been, a registered health practitioner (for example, a doctor, nurse, midwife, dentist, pharmacist);
• involved in conducting health or disability research or who is employed by a health agency and who is in a sector of that agency which undertakes health research, or
• construed by virtue of employment, profession or relationship to have a potential conflict or professional bias in a majority of protocols reviewed.

Member categories

Lay membership shall include:
• an ethicist
• a lawyer
• consumer perspectives
• community perspectives.

Non-lay membership shall include:
• two health researchers
• a pharmacist or pharmacologist
• a biostatistician
• two health practitioners.

Gender balance should be as close to half male and half female as practicable.

If the ethics committee is reviewing clinical research, the HRC Ethics Committee requires at least two members to be clinicians, at least one of whom is currently in active practice.

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 Operational Standard and/or the HRC 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 Ethics Committee has developed a policy to address such situations of imbalance. As a general principle, the appointment of the Māori member will take precedence over other considerations of balance. The lay / professional and gender balance of the committee will be taken as secondary issues in this instance. The order of priority is - Māori, gender, lay versus professional, other cultural considerations.

Whole committee requirements

At any time, consistent with the requirements of the New Zealand Public Health and Disability Act requirements for District Health Boards, the HDEC shall have at least two Māori members. Māori members should have a recognised awareness of te reo Māori, and an understanding of tikanga Māori. All members of the HDEC are expected to have an understanding of how the health sector responds to Māori issues and their application to ethical review.
Appendix 1   Accreditation for Health and Disability Ethics Committees

HDEC's should include expertise in the main kinds of health and disability research (e.g. interventional, observational, kaupapa Māori, and social research), and in both quantitative and qualitative research methods.

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 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 HDEC as equal individuals of sound judgement, relevant experience and adequate training in ethical review.

2. Terms and Conditions of Appointment

Members of HDECs are appointed by the Minister of Health pursuant to section 11 of the New Zealand Public Health and Disability Act 2000, for a term of office of up to three years. The terms of office of members of HDECs shall be staggered to ensure continuity of membership. Members may be reappointed from time to time. No member may hold office for more than six consecutive years. After serving the maximum six-year term, members shall not be considered for reappointment until at least three years after their retirement from the HDEC.

3. Chairperson and Deputy Chairperson

The Minister shall appoint a member of the HDEC to be its Chairperson. The terms and conditions of appointment for members of the HDEC also apply to the person appointed as Chair. The Chairperson shall preside at every meeting of the HDEC at which they are present.

The HDEC shall appoint a non-lay member as Deputy Chairperson.

The Chairperson and Deputy Chairperson may act with the delegated authority of the HDEC between meetings.

4. Decision making process

Wherever possible, the HDEC should determine matters by consensus decision. Where a consensus cannot be reached, a vote shall apply, with a two-thirds majority of those voting required for any decisions, and the Chairperson having a casting vote.
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 an HDEC meeting or for those members views to be sought and represented at the meeting, the matter should be deferred.

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.

In order for ethics committees to be able to function with a consensus decision-making approach members of committees must be free to participate fully in discussion and debate. In particular, the chairperson needs to have established skills in consensus decision-making.

It is important to note that members may wish to consult on ethical issues with, for example, individuals, groups, iwi and hapu, and this should be supported and encouraged. 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.

5. Applications for Accreditation and Reaccreditation

Applications to the HRC should include:

Membership

A list of members of the committee indicating –

- the categorisation of each member on the committee (e.g. Chair, health professional/lay, Māori);
- the areas of expertise or experience which each member brings to the committee (e.g. ethics, law, theology, community involvement, medical practice, health research);
- the gender of each appointed member;
- The date of appointment of each member and date of retirement from the committee, noting if renewable;
- the professional affiliation (if any) of each member, and
- 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).

Policies and Procedures
The Policies and Procedures for the HDEC, should be provided and include the following -

- Terms of Reference;
- the decision making process;
- details of any fast track procedures;
- details of research activities for which Ethics Committee approval would not be required;
- details of the complaints procedure;
- details of research activities for which expedited review is available;
- details of the lines of reporting and responsibility to and from its parent body, and
- for reaccreditation, any changes that have been made to the Terms of Reference since the previous accreditation should be identified and described.

Responsiveness to Māori

In order for accreditation and reaccreditation to be considered, committees should highlight how they implement Sections 1.4 and 1.5 of the Operational Standard in terms of informed input, shared decision-making and support mechanisms given to ensure all committee members share the responsibility of working towards improving Māori health outcomes and reducing health inequities for Māori, and thus giving value to the principle provisions of the Treaty of Waitangi.

Ethics Committee Guidelines

For accreditation purposes HDECs should provide their Terms of Reference and state the guidelines under which the ethics committee will operate. All guidelines should be noted, for example, the Operational Standard, HRC Ethics Committee Guidelines, Code of Health and Disability Services Consumers’ Rights, and Health Information Privacy Code).

6. Annual Reporting (for Continued Accreditation)

Accreditation is for a 3 year period. During this period HDECs provide an annual report, through the Ministry of Health, to the HRCEC for review and monitoring in order to maintain their accredited status.

Annual Reports are required by the HRC Ethics Committee by 1 April of each year for consideration at the May meeting of the Committee. Prior to this meeting each report will have been reviewed by a member of the HRC Ethics Committee who will make a report.

The committee guidelines/policies and procedures are not required as part of the annual reporting process, unless they have been amended.

Ethics Committee reporting falls into two categories: 
Appendix 1   Accreditation for Health and Disability Ethics Committees

(1) reports on matters of administration, appointments, workload and any other aspects of the committee’s operations deemed to be significant, and

(2) reports on substantive matters of ethical concern.

The Annual Report should include the following:

1. A list of the research and innovative treatment protocols reviewed in the preceding year, including –
   - the title of the research;
   - the name of the principal investigator;
   - the name of the institution where the research is to be/has been undertaken;
   - the date of the first review;
   - the date of the final outcome, and
   - the outcome (which is likely to be one of the following: approved, approved subject to conditions, deferred or declined).

   This list may be structured in any order, and may include more but not less than this information. In compiling their reports, ethics 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.

2. A summary of the total numbers of applications reviewed, subdivided into the outcome areas.

3. Explanatory comments on declined proposals or those that required a significant amendment.

4. Comments on how the applications has been responsive to Māori including -
   a) How many applications were deferred because the HRC Booklet “Guidelines for Researchers on Health Research involving Māori” were not read?
   b) The number of applications for which consultation with Māori/iwi/hapu was considered to be appropriate?
   c) How many applications were returned through no/insufficient consultation with appropriate Māori/iwi/hapu?
   d) The processes the Committee has for following through on the consultation?
   e) Details of any cases where unsatisfactory reasons were given for not including Māori in research?
   f) An account of the mechanisms that have been set up to facilitate consultation with Māori on the part of the researchers.
Appendix 1   Accreditation for Health and Disability Ethics Committees

5. Any changes in the ethics committee membership or guidelines for operation, or other substantive changes which the committee or its Chair feels should be noted (for example, restructuring in the parent organisation which might affect the ethics committee’s operation).

6. The meeting date at which the Ethics Committee adopted the annual report.

7. A separate and complete membership list (as provided for accreditation) with commencement and end of term dates. It is especially important to indicate expertise of new members and it is also preferred that the Māori members’ iwi are noted.

8. A schedule of the attendance of individual members at meetings with an explanation of absences if appropriate, including –
   - an indication if the member is lay or non-lay;
   - an indication if the member is Māori;
   - the monthly total of members attending each meeting;
   - the total number of meetings each member attended, and
   - the number of protocols reviewed at each meeting.
   A template for this schedule is available from the HRC.

9. The criteria used by the chair to exercise delegation.

10. A description of the procedures used to orient and train new members of the committee.

11. A description of provisions made for ongoing training and attendance at training, or other conferences and seminars for committee members, and how many members of the committee participated in training opportunities during the year.

12. The complaints procedure used by the ethics committee including a description of how complaints are investigated and resolved, as well as referral for second opinions where relevant.

13. A list of complaints received by the ethics committee (if any), the actions taken to resolve the complaint and a comment upon the outcome of the complaint.

14. Any areas of review which caused difficulty for the committee in making a decision on any particular protocol(s), and any questions on policy or other matters which the committee may wish to put to the HRC Ethics Committee for comment or guidance.

15. If desirable, the Chair of the ethics committee may forward a separate confidential comment to the HRC Ethics Committee noting any special concerns, requests or comments.
Appendix 2

Accreditation for Institutional Ethics Committees

Institutional Ethics Committees (IECs) are established by organisations, such as universities or private companies and review research applications directly related to the organisation or their agent. While the principles of the Operational Standard for Ethics Committees (Operational Standard) apply to IECs, often the research that they review is not health related and they have policies and procedures that reflect the nature of the research that they review.

The HRC recognises that for accreditation purposes, not all the expectations applied to HDECs apply to IECs and that there may be particular requirements for IECs which do not apply to HDECs.

The following sections set out the requirements for accreditation for IECs and include explanatory notes on aspects of the functioning of IECs which may be helpful to them. This Appendix considers:

- Composition and membership
- Terms and conditions of appointment
- Chairperson
- Decision making process
- Standards for the conduct of research
- Applications for Accreditation and reaccreditation processes
- Annual Reporting (for continued accreditation)

1. Composition and Membership

Guiding principle

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

The membership requirements for an IEC should be set out in its Policies and Procedures. Membership should reflect the knowledge and expertise that an IEC requires to ensure (1) the protection of research participants, and (2) the enhancement of public confidence in the system of ethics review.

As far as possible, to achieve these goals, membership of the committee should be capable of ensuring a review which is robust, expert, and includes an element of independence from the institution.
A membership composed solely of members of the institution could present a situation where the interests of research participants were, or were perceived to be, placed second to the interests of the institution. Hence, IECs should ensure that they have appropriate external representation. A range of perspectives, experience and expertise should also be represented.

**Member numbers**

To be able to achieve the required range of membership, the HRC Ethics Committee considers the minimum number of members should be 10. It is noted that the Operational Standard specifies that the number of members should be 12. Nevertheless, it is the range of expertise and representation that matters, and it is this aspect that the HCR Ethics Committee particularly takes into account.

**Make up of the committee**

Given this perspective, the categories into which membership should fall, and the number of members in each category, should generally be as follows:

<table>
<thead>
<tr>
<th>Categories</th>
<th>Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expertise</td>
<td></td>
</tr>
<tr>
<td>Tikanga Māori</td>
<td>1</td>
</tr>
<tr>
<td>Research areas regularly reviewed including qualitative and quantitative expertise</td>
<td>1 for each</td>
</tr>
<tr>
<td>Ethics (with formal training)</td>
<td>1</td>
</tr>
<tr>
<td>Law (preferred)</td>
<td>1</td>
</tr>
<tr>
<td>Community</td>
<td></td>
</tr>
<tr>
<td>Wider community (non-Institution)</td>
<td>2</td>
</tr>
<tr>
<td>The Māori community</td>
<td>2</td>
</tr>
<tr>
<td>The student community</td>
<td>1</td>
</tr>
</tbody>
</table>

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

Gender balance should be as close to half male and female as practicable.

**Consultation Outside the Committee**

The HRC 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. The HRC Ethics Committee supports and encourages such consultation.
For example, on ethical issues this may be with individuals, groups, iwi and hapu. 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 may not participate in the decision making process.

**Membership for Committees Reviewing Health Related Protocols**

Some IECs may review low risk health research. The HRC Referral Guidelines sets out the research that IECs should refer to an HDEC. Some IECs may review health related research in accordance with the HRC Referral Guidelines. If they do, in addition to the membership requirements mentioned earlier, at least three members must be appropriately qualified health professionals, of whom at least two shall be clinicians and one in active practice.

2. **Terms and Conditions of Appointment**

The HRC takes the view that a systematic turnover of members is important for the effective functioning of an IEC over time. But it is also aware that there may be practical difficulties in recruiting members in some categories, and of the value of experienced members of the committee.

Following the timeframes set out for HDECs and the HRC Ethics Committee members, it is recommended that members of IECs 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 Ethics Committee will consider an extension of an appointment beyond six years where the effectiveness of the committee would otherwise be compromised.

3. **Chairperson**

Ideally, the committee should be chaired by someone with no affiliation to the Institution. However, if it is not possible or feasible for such an appointment to be made, 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. The chair needs to have established skills in consensus decision-making.

4. **Decision making process**

**Review Processes**
The HRC Ethics Committee has a preference for ethics committees to meet face-to-face because it believes that such interaction best ensures robust and thorough review. While the HRC Ethics Committee recognises that non-health research may not involve the same risk to participants as health research, it believes the same principles of ethical approval apply to all categories of research.

However, other means of review will be considered for accreditation. The HRC Ethics Committee recognises that IECs have a range of review processes, such as:

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

For accreditation, the HRC Ethics Committee must be satisfied that the process ensures robust review. The IEC will need to provide convincing evidence that this is the case.

**Preference for Consensus Decision Making**

The HRC Ethics Committee prefers consensus decision-making, because it believes aiming for this process is more likely to reflect the full range of views on the committee. In order for an IEC 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.

The Operational Standard states that “Where a consensus cannot be reached, a vote shall apply, with a two-thirds majority of those voting required for any decisions, and the Chairperson having a casting vote.” Other methods of decision making are possible (such as voting) but these need to be justified for accreditation.

**Other Processes**

To be accredited, IECs will need to detail any variations to normal processes of review, for example, for any fast-track (expedited) review, variations for particular protocols (e.g. student research projects, key informant interviews), chairman’s action, and so on.

The HRC Ethics Committee will need to be satisfied that a complaints procedure is in place.
5. Standards for the conduct of research

The HRC Ethics Committee will need to be reassured that IECs seeking accreditation are applying nationally/internationally accepted standards for the conduct of research (including recruitment, informed consent, privacy and protection from harms). The HRC Ethics Committee would expect these standards to be set out in the policies on research which the IEC operates under. These should be Institutional Policies.

For accreditation review purposes, IECs should state the guidelines for researchers which the IEC will apply. All national and international guidelines to which the organisation adheres should be referenced (for example, the Operational Standard, the HRC Ethics Committee Guidelines for Ethics in Health Research, the Code of Health and Disability Services Consumers’ Rights and the Health Information Privacy code).

Through the process of accreditation, the HRC Ethics Committee will review the IECs Policies and Procedures and may suggest revisions if necessary for accreditation to be approved.

It is expected that the policies and procedures will cover the need for ethical review of all research carried out by staff of the institution that requires ethical review and that there are processes and policies for dealing with failure to do so.

6. Applications for Accreditation and Re-accreditation

In order for an application for accreditation or re-accreditation to proceed, the HRC Ethics Committee requires sufficient documentation to satisfy it that the IEC is able to offer sufficient protection to the research subjects and maintain the reputation of ethical review in general.

Applications should cover both the membership, process requirements and ethical standards set out in sections 1, 4 and 5 of this Appendix. In support of these, the application should include documentation relating to the following:

Membership

A list of members of the committee indicating:

- the status of each member of the committee as internal or external to the institution;
- the areas of expertise or experience which each member brings to the committee (e.g. ethics, law, research, theology, tikanga Māori);
- community membership (e.g. Māori, student);
Appendix 2   Accreditation for Institutional Ethics Committees

- the gender of each appointed member;
- the date of appointment of each member and date of retirement from the committee, noting if renewable;
- the professional affiliation (if any) of each member, and
- 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).

Policies and Procedures

A complete set of Policies and Procedures, outlining the decision making process, including:

- the functions of the Committee;
- the Terms of Reference of the Committee;
- the method of application;
- descriptions of normal procedures for review;
- descriptions of any variations to the normal procedures;
- the decision-making process;
- the kind of applications which require ethical approval;
- the kind of applications which do not require ethical approval;
- details of any fast track procedures, including the types of research activities that can be approved by expedited review;
- details of any research activities approved by delegated committees of the IEC or other means (e.g. at departmental level) and the lines of reporting to the IEC;
- details of the complaints procedure;
- details of the process for dealing with researchers who do not obtain appropriate ethical review of their research, and
- for reaccreditation, any changes to Policies and Procedures that have been made since the previous accreditation should be noted and highlighted.

Responsiveness to Māori

In order for accreditation and reaccreditation to be considered, committees should provide a brief profile of their committee’s strategic policy in ensuring Treaty and Māori responsiveness. This may include the organisation’s policy on Treaty and Māori responsiveness relative to the core activity of the committee or the strategic policies specific to the committee. In both cases, committees are requested to highlight how the ethics committee implements the relationship in terms of informed input, shared decision-making, recruitment of members and support mechanisms given to ensure all committee members share the responsibility of working towards improving Māori health outcomes and reducing health inequities for Māori, and thus giving value to the principle provisions of the Treaty of Waitangi.

Ethical Standard
Indications of the guidelines which the IEC applies and copies of any institutional policies, such as:

- 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;
- procedures relating to confidentiality and privacy;
- procedures relating to risk of harm;
- remuneration of participants, and
- compensation for injury or harm.

Reporting lines

A statement 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).

7. Annual Reporting (for continued accreditation)

Accreditation is for a 3 year period. During this period IECs provide an annual report to the HRC for review and monitoring in order to maintain their accredited status.

Annual Reports from IECs are required by the HRC Ethics Committee by 1 April (for 31 December year end) or by 15 September (for 30 June year ends) of each year for consideration at the May or October meetings of the Committee. Prior to this meeting each report will have been reviewed by a member of the HRC Ethics Committee who will make a report.

Ethics Committee reporting falls into two categories:

(1) Reports on matters of administration, appointments, workload and any other aspects of the committee’s operations deemed to be significant, and
(2) Reports on substantive matters of ethical concern.

The policies and procedures and ethical guidelines which the IEC applies are not required as part of the annual reporting process, unless they have been amended. Any amendments should be explicitly drawn to the attention of the HRC Ethics Committee.

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

The Annual Report should include the following:
1. A list of the research and innovative treatment protocols reviewed in the preceding year, including -
   • the title of the research;
   • the name of the principal investigator;
   • the name of the institution where the research is to be/has been undertaken;
   • the date of the first review;
   • the date of the final outcome, and
   • outcome (which is likely to be one of the following: approved, approved subject to conditions, deferred or declined).

   This list may be structured in any order, and may include more but not less than this information. In compiling reports, IECs should take care not to provide information which would involve a breach of the Privacy Act 1994 and/or the Health Information Privacy Code 1994.

2. A summary of the total numbers of applications reviewed, subdivided into the outcome areas.

3. Explanatory comments on declined proposals or those that required a significant amendment.

4. Comments on how the applications have been responsive to Māori comments including -
   a) How many applications were deferred because the HRC Booklet “Guidelines for Researchers on Health Research involving Māori” were not read?
   b) The number of applications for which consultation with Māori/iwi/hapu was considered to be appropriate.
   c) How many applications were returned through no/insufficient consultation with appropriate Māori/iwi/hapu?
   d) The processes the Committee has for following through on the consultation.
   e) Details of any cases where unsatisfactory reasons were given for not including Māori in research.
   f) An account of the mechanisms that have been set up to facilitate consultation with Māori on the part of the researchers.
   g) Any examples of Māori not being included in research.

5. Any changes in the ethics committee membership or guidelines for operation, or other substantive changes which the committee or its Chair feels should be noted (for example, restructuring in the parent organisation which might affect the ethics committee’s operation).
6. The meeting date at which the Ethics Committee adopted the annual report.

7. A separate and complete membership list (as provided for accreditation) with commencement and end of term dates. It is especially important to indicate expertise of new members and it is also preferred that the Māori members’ Iwi is noted.

8. A schedule of the attendance of individual members at meetings with an explanation of absences if appropriate, including:
   - an indication if the member is internal or external;
   - an indication if the member is Māori;
   - the monthly total of members attending each meeting;
   - the total number of meetings each member attended, and
   - the number of protocols reviewed at each meeting.

A template for this schedule is available from the HRC.

9. The criteria used by the chair to exercise delegation.

10. A description of the procedures used to orient and train new members of the committee.

11. A description of provisions made for ongoing training and attendance at training, or other, conferences and seminars for committee members, and how many members of the committee participated in training opportunities during the year.

12. The complaints procedure used by the ethics committee including a description of how complaints are investigated and resolved, as well as referral for second opinions where relevant.

13. A list of complaints received by the ethics committee (if any), the actions taken to resolve the complaint and a comment upon the outcome of the complaint.

14. Any areas of review which caused difficulty for the committee in making a decision on any particular protocol(s), and any questions on policy or other matters which the committee may wish to put to the HRC Ethics Committee for comment or guidance.

15. If desirable, the Chair of the ethics committee may forward a separate confidential comment to the HRC Ethics Committee noting any special concerns, requests or comments.
Appendix 3

References to Guidelines, Legislation, Regulations and Codes

HRC Guidelines
- HRC Guidelines on Ethics in Health Research (revised 2005)
- HRC Guidelines for an Accredited Institutional Ethics Committee to refer Studies to an Accredited Health and Disability Ethics Committee (Referral Guidelines)

Other Guidelines
- Operational Standard for Ethics Committees (MoH 2002, updated 2006)

Legislation
- Injury Prevention, Rehabilitation, and Compensation Act 2001
- Health Research Council Act 1990
- Official Information Act 1982
- Privacy Act 1993
- Human Rights Act 1993
- Public Records Act 2005

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

Codes
- Health Information Privacy Code 1994
- Interim New Zealand Guidelines for Good Clinical Research Practice