Guidelines for an Accredited Institutional Ethics Committee to refer Studies to an Accredited Health and Disability Ethics Committee ("Referral Guidelines")

Guidelines of the HRC Ethics Committee

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There are two types of accredited ethics committees that can review health and disability research :

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

The Referral Guidelines are intended to clarify when an IEC should refer a health research study to an HDEC for review.

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

1. The Primary and Over-riding Guideline

1.1 The primary and over-riding guideline is that applications should be reviewed by an accredited committee with the expertise required to evaluate the application, and to identify risks and adequate protections for participant.

1.2 Where there is any doubt, an IEC should refer the study to an HDEC.

2. Approval required from HDEC

Approval from an HDEC is required for the following:

2.1 Any clinical trial involving the Standing Committee on Therapeutic Trials (SCOTT) or the Gene Technology Advisory Committee approval (GTAC), for example, when submitting a clinical trial application under section 30 of the Medicines Act[1].

2.2 Any clinical trial sponsored by and/or for the benefit of the manufacturer or supplier of a drug or device, i.e. trials requiring completion of Statutory Declaration B for the *National Application Form for Ethical Approval*[2].

2.3 Any research using established human embryonic stem cell lines.[3]

2.4 Any research study which involves participants who are patients/clients of any organisation providing health services (for example, general practice, physiotherapy, occupational therapy, sports medicine), disability services, or institutionalised care, and:

(a) The IEC lacks the clinical or other expertise to make and appropriate ethical judgement, and is unable to obtain the appropriate expertise for reviewing that research; or

(b) The study poses risk of more than minimal harm to participants; or

(c) There is a real or apparent conflict of interest which would prevent the IEC from providing independent review.[4]

2.5 Any research study (including clinical trials) which involves District Health Board staff or the use of District Health Board facilities, or which is supported directly or indirectly in full or in part by District Health board funds. Such research study may, however, be reviewed by an IEC if:

(a) there is *mutual agreement* between the regional HDEC (in the region where the IEC is located) and the IEC for that to happen;
(b) the IEC has the *appropriate expertise* to review such research; and
(c) the research is *not* a study of the kind referred to 2.4 above.

2.6 Any research study which requires ethical approval to access information about the health or disability of any identifiable individual held by the Ministry of Health, or held by any public or private organisation whether or not that organisation is related to health, and the study poses risk of more than minimal harm to participants.

2.7 Any research study involving the collection of human tissues (for example, blood, muscle) where the research study is to be reviewed by an IEC which does not have a health professional present at the discussion who is qualified to assess the safety of the procedures (see Guidance Notes, 3.2. and 3.7, below).

3. Guidance Notes

3.1 IECs should always be vigilant in focusing on the protection of participants and any relevant health information involved, and reflect on whether it would be more appropriate, in accordance with these guidelines, for any research study that is being reviewed to be referred to a HDEC.

3.2 IECs 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 adequate protections for the participants. IECs reviewing health research would normally be expected to have a minimum of two registered health professionals with the appropriate expertise.

3.3 IECs and regional HDECs should advise each other of their approving or declining of any application which could be considered of relevance to either of them, for example an application to a regional HDEC involving an Institutional staff member.

3.4 It is recognised that in some circumstances an HDEC may refer an application to an IEC where approval is not required by an HDEC and it is considered that an IEC is the most appropriate committee to review the application.

3.5 IECs and regional HDECs should agree on the policies and procedures that should apply in their region to address the issues set out above. The policies and procedures should cover all health research studies that involve human participants, and not just those deemed to be clinical trials. The policies and procedures should be made available to the research community as part of the guidelines for applications for ethical approval.

3.6 No research study should commence until after it has been approved by an accredited ethics committee, and where appropriate, referred to and approved by an accredited HDEC consistent with these guidelines.

3.7 Ethical approval for a research proposal must be obtained from a single accredited ethics committee which is able to review a research proposal as a whole. Where part of a research proposal should be approved by a HDEC, the whole of the proposal should be referred to that committee.

3.8 It is recognised that there may be limited circumstances where an IEC and a regional 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.

3.9 The collection of human tissues to form part of an institutional anatomical collection should be dealt with in accordance with the Human Tissue Act 1964.

3.10 IECs should be encouraged to seek advice for review of studies that fall outside their jurisdiction or region and be aware of potential issues.

3.11 Expedited ethics committee review may be appropriate if it is minimal-risk observational research or an audit or related activity that requires ethics committee review.[5]

4. Review of Guidelines

4.1 It is recognised that cases may arise where exceptions to these guidelines may have to be considered and so the HRC Ethics Committee should be informed accordingly in order that they can be discussed when future reviews and revisions of the guidelines are undertaken.

4.2 The HRC Ethics Committee will conduct a review no later than 24 months after publication of these guidelines.

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[1] Section 30 of the Medicines Act 1981: **Exemption for clinical trial** – (1) Notwithstanding section 20 or section 24 of this Act, but subject to the succeeding provisions of this section, the importer or manufacturer in New Zealand of any medicine may distribute it for the sole purpose of obtaining clinical and scientific information with respect to its safety and efficacy, if the clinical trial, and the persons (in this section called the investigators) who will conduct the trial, have been approved by the Director-General on the recommendation of the Health Research Council of New Zealand.

[2] Statutory Declaration B: **Declaration of provision for compensation for injury for participants in a research study for a pharmaceutical company or any other company involved in health research.** Statutory Declaration B is to be completed by research applicants conducting a research study which is principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out.

[3] p5, Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research, Ministry of Health, 2006 (http://www.newhealth.govt.nz/ethicscommittees/documents/guidelines-stem-cell-use.pdf)

[4] 6.2 Principles of Natural Justice, Operational Standard for Ethics Committees, MoH, 2002, updated 2006

[5] Ethical Guidelines for Observational Studies – Observational Research, Audits and Related Activities – National Ethics Advisory Council – December 2006