

1.1.10 Ethics Committee Induction Information

Alfred Hospital Ethics Committee

Induction Information 2010

From **The Human Research Ethics Handbook – Commentary on the National Statement on Ethical Conduct in Research Involving Humans** (now revoked but still a useful source of information) <http://www.nhmrc.gov.au/publications/hrecbook/misc/contents.htm>

The following information about relevant considerations when reviewing research has been updated to include references to the current National Statement (2007).

Relevant considerations for reviewing research:

HRECs need to be satisfied that the research design can produce valid results and can protect the welfare and rights of research participants. To be satisfied, an HREC may seek or receive advice from an individual, a scientific committee in its institution, an external expert, or it may include an *additional* person who has specific expertise in the particular type of research. For more information on research design, see the Research Ethics Collection, ' [Research, design and purpose](#) ' page E143.

It is not possible to provide a comprehensive list of relevant considerations for every research approval. However, the following matters will usually require consideration:

The project

- Is there a clear hypothesis?
- Is the research question useful? Is the research worthwhile?
- Is the research likely to yield new information, enhance understanding or clarify existing uncertainty?
- Has this, or similar, research been carried out before in the same, or similar, contexts?
- Can the research proposal be supported by a systematic review of the literature that would demonstrate the importance of the research question and that it builds upon the results of previous research?
- If indicated, have perspectives of potential participant groups, the wider community, or other disciplines been incorporated into the research proposal?
- Are the aims of the proposal clear?
- Does the value of the project appear to be adequate to justify its conduct with humans?

The researchers

- Do the researchers have necessary qualifications, competence and experience?
- Are there adequate arrangements to ensure that members of the research team are aware of relevant ethical and legal obligations?

The funding

- What is the relationship between the source of funding and the aims of the project?
- Does that relationship have any implications for the ethical conduct of the project, especially the recruitment of participants, the character of information sought or the freedom to publish the results?

Other HREC approval

- Where applicable, are the reasons given by another HREC, either for approval or the imposition of conditions, consistent with the HREC's own opinion?

Research methodology

- Are all aspects of the research methodology clearly described?
- Is the HREC satisfied that the methodology is appropriate to the achievement of the aims of the project?

Recruitment of participants

- Is it clear how participants will be recruited?
- Do the recruitment methods respect participants' rights to the confidentiality of their affairs?
- Are the proposed participants appropriate in number and kind?

Burdens of research

- Are the burdens and risks of research to participants clearly identified and have appropriate measures been taken to minimise these?
- Is the balance between the burdens and risks to participants and the aims and benefits of the project such as to warrant approval?

Incentives for participation

- Are financial or other rewards proposed to be given to participants?
- Are these of such a size or value that they may unduly influence the freedom of participants to withdraw or otherwise protect themselves from risks?

Consent

- Are the ways in which participants will be approached clearly described?
- Is the information to be provided to potential participants adequate in content and appropriate in form?
- Do the proposed methods of securing consent to participate provide a) sufficient time to consider the decision; b) evidence that participants understood their choices, and c) sufficient opportunities to ask questions and re-consider?

Discontinuing participation

- Are the ways in which participants are advised of their freedom to withdraw sufficient in content and frequency?

Information protection

- Is it clear who will (and who will not) have access to information collected during the project?
- Are the proposed storage and security measures adequate?
- Are participants clearly informed that information they provide will be used only for the project?
- What measures are proposed to protect the confidentiality of information in the course of the project and are these adequate to give the degree of protection promised to participants?
- Are the manner and form in which results will be published clearly described, and do they adequately protect the confidentiality of information and privacy of participants?

Legal issues

- Does the project involve subject matter or conduct which may give rise to legal vulnerability of participants or researchers? Are adequate precautions to be taken?

1.1.10 Ethics Committee Induction Information

In addition to these recurrent issues, some research requires particular additional attention, either because of the vulnerability of the intended participants or the type of research. Research with vulnerable participants that needs additional consideration includes:

- Women who are pregnant and the human foetus (see NS 4.1);
- research involving children (see NS 4.2);
- research involving persons in dependent or unequal relationships (see NS 4.3
- research involving persons in highly dependent medical care situations (see NS 4.4);
- research involving participants with intellectual or mental impairment, including temporary impairment, for example as a result of alcohol or drug-induced intoxication (see NS 4.5);
- research involving people who may be involved in illegal activities (see NS 4.6)
- research involving Aboriginal or Torres Strait Islander communities (see NS 4.7 which refers to *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC 2003));
- research involving people in other countries (see NS 4.8)

Types of research requiring additional attention include:

- research involving ionising radiation
- research involving assisted reproductive technology
- clinical trials (NS 3.3)
- epidemiological research
- research using human tissue samples (NS 3.4)
- human genetic research (NS 3.5)
- research involving deception (NS 2.3)

INFORMATION FOR HSS ETHICS COMMITTEE MEMBERS

Background Information

Ethical Guidelines:

National Statement on Ethical Conduct in Human Research
<http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>
Australian Code for the Responsible Conduct of Research
<http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>
AMREP Guidelines to Good Clinical Practice
<http://www.alfredresearch.org/policies/GCRP.pdf>
The Alfred Health Research and Ethics website <http://www.alfredresearch.org/ethics.htm>
Human Research Ethics Handbook (this explains the old NS but is still useful)
http://www.nhmrc.gov.au/publications/hrecbook/01_commentary/contents.htm

Legislation:

Health Services Commissioner's Statutory Guidelines on Research (Vic)
<http://www.health.vic.gov.au/hsc/legislation.htm>
Guidelines Under Section 95 and Section 95A of the Health Records Act (Comm)
<http://www.nhmrc.gov.au/publications/synopses/e26syn.htm>
<http://www.nhmrc.gov.au/publications/synopses/e43syn.htm>
Guardianship and Administration Act (Vic)
http://www.austlii.edu.au/au/legis/vic/consol_act/gaaa1986304/
<http://www.health.vic.gov.au/legislation/medicalresearch> (good summary)
Human Tissue Act (Vic)
<http://www.health.vic.gov.au/humantissue/htact>

Main Ethics Application Forms:

- Common Application Form (DHS) – used by many Victorian public hospitals and other organisations; comprised of a number of modules <http://www.alfredresearch.org/ethics/applicat.htm>
- NEAF (National Ethics Application Form) (NHMRC) – increasingly being used by many organisations, especially where multiple sites/centres and more than one state. The main form is accompanied by a State Specific Form and a Site Specific Form
<https://www.neaf.gov.au/default.aspx>
- Low Risk Application Form (Alfred Health) (shorter form for research where risk to participants is no greater than inconvenience)
<http://www.alfredresearch.org/ethics/applicat.htm>
- Amendment Application Form (Alfred Health) – for changes to research that has already received ethics approval
<http://www.alfredresearch.org/ethics/amend.htm>

Ethics Review Process

1. Initial/draft submission
2. Full application (**on CD1 & 2 and in hard copy for primary reviewers**)
3. Pre-meeting changes, if any (**on CD2, in 'Reviews & Responses' folder**)
4. Meeting
5. Post meeting change, if any (**emailed to primary reviewers after meeting**)
6. Approval

Reviewing Projects

1. Projects are allocated 2 primary reviewers, who read the application closely
2. Primary reviewers email comments, questions, requests for changes and clarifications to Ethics Office
3. Ethics Officers advise researchers of reviewers' comments (keeping identity of reviewers confidential)
4. Researchers respond, addressing all points
5. Primary reviewers check CD2 for the researchers' responses to their questions/issues
6. Reviewers present 'their' project/s at meeting and Committee discusses

1.1.10 Ethics Committee Induction Information

7. All members should read at least the PICF and/or lay summary for every H&SS project before the meeting.

Reviews:

There is no pro-forma but many Committee members use the following structure:

- Summary of key features of project - what it's about, what is involved for participants.
- Main ethical issues raised by project/considered by the reviewer
- Questions/requests for changes for researchers – it's helpful if these are worded as if you are addressing the researcher (i.e. as formal questions)
- Issues for discussion at the meeting, if you want to seek the opinion of other members.

In the H&SS folder on the CD, there are reviewers' instructions and a generic Checklist of the more significant ethical issues commonly raised by H&SS projects.

Reviews are emailed to the Ethics Officers:

s 47F and s 47F

Deadlines:

Month	Date you will receive CD1 and hard copy projects	Date your review/s are due	Date you receive CD2 to check researchers' responses	Date of main Ethics Committee meeting
February	5 Feb	11 Feb	19 Feb	25 Feb
March	5 Mar	11 Mar	19 Mar	25 Mar
April	9 Apr	15 Apr	23 Apr	29 Apr
May	7 May	13 May	21 May	27 May
June	4 Jun	10 Jun	18 Jun	24 Jun
July	2 Jul	8 Jul	16 Jul	22 Jul
August	6 Aug	12 Aug	20 Aug	26 Aug
September	3 Sep	9 Sep	17 Sep	23 Sep
October	1 Oct	7 Oct	15 Oct	21 Oct
November	5 Nov	11 Nov	19 Nov	25 Nov
December	26 Nov	2 Dec	10 Dec	16 Dec

Amendments

After a project is approved, the researcher may want/need to change various aspects of the research. They do this via an amendment application, consisting of an amendment application form and relevant project documents (eg. PICF, protocol, etc.)

The amendment application goes to the two primary reviewers for that project, usually in hard copy and sometimes via email. There is a cream-coloured cover sheet for your review and recommendations, and instructions for when your review is due and which Ethics Officer to send it to.

Reviewers are given 8 days to review amendments.

Projects for Low Risk review, Expedited review and Cross Approval

These applications are reviewed out-of-session and approval is endorsed at the next EC meeting.

Low Risk review: rotated through the Committee; you will receive several per year; instructions for reviewers are included with the application documents.

Expedited review: for 'lower risk' projects which need urgent review/approval (eg. Swine flu projects); these usually come on the initiating institution's ethics application form.

Cross Approval: for 'lower risk' projects that have already been reviewed and approved by another NHMRC-registered Ethics Committee; these usually come on the initiating institution's ethics application form.

CHECKLIST OF ETHICAL ISSUES REQUIRING SPECIAL ATTENTION

Privacy Issues*

- ☐ Collection of identified information *without* gaining participant/guardian consent
- ☐ Use of identified information *without* gaining participant/guardian consent
- ☐ Disclosure of identified information *without* gaining participant/guardian consent

*What is the researcher's justification and is it adequate?
Please report on this at the meeting – it helps with the annual report to AHEC.

Minors

- ☐ Involves participants under 18 years **without** parental/guardian consent

*Is the researcher's justification adequate?
Are processes to determine competence and gain consent appropriate?*

Participants with impaired capacity to consent

- ☐ Highly dependent on medical care
- ☐ Mentally or intellectually impaired
- ☐ Emergency situations

Consent procedures involve:

- Person Responsible consent **Y / N**
- Procedural Authorization **Y / N**
- Emergency Enrolment **Y / N**

Is the researcher's justification adequate? Are the consent procedures appropriate?

Sensitive Issues

- ☐ Questionnaire-based research involving sensitive or highly personal information
- ☐ Collection of specific and substantial sensitive data about third persons without their consent
- ☐ Genetic analysis of medical or social* significance to relatives (*eg. paternity)
- ☐ Subject matter or conduct that may give rise to legal vulnerability of participants or researchers
- ☐ Contact with relatives of deceased patients
- ☐ Deception of participants
- ☐ Indigenous populations

*a) Is it necessary to the research, and/or
b) are the approach to participants, procedures and researchers suitable?*

External Sites

- ☐ Alfred Hospital Ethics Committee is responsible for sites external to the hospital, eg. GPs

Are recruitment procedures a) adequately explained, and b) appropriate?

External Data Collector

- ☐ Data collection being outsourced eg. conducted by a research company
- ☐ Data collection from medical records not being done by an Alfred staff member

Are credentials and data security adequate? Are participants informed in the PICF?

Other ☐

Are there any other SIGNIFICANT issues that should be raised at the meeting?