Operations Manual for the

Human Research Ethics Committees (HRECs)

August 2010
Document Control

Approval of this Manual and confirmation that it describes the policies and procedures implemented by the HRECs and Ethics Secretariat:

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<tr>
<th>NAME</th>
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<tr>
<td>Professor Les Field</td>
<td>Deputy Vice Chancellor (Research)</td>
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Version Control

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Version 2: August, 2010
Preamble

This Operations Manual is intended to describe the process of human research ethical review at the University of New South Wales. Its objective is to facilitate the conduct of the Human Research Ethics Committees (HRECs), Human Research Ethics Advisory (HREA) Panels and the Ethics Secretariat so that quality and consistency in ethical review and associated processes are maintained. The existence of clear and easily accessed written working policies and procedures is required by the *National Statement on Ethical Conduct in Human Research (2007)* [http://www.nhmrc.gov.au/guidelines/publications/e72](http://www.nhmrc.gov.au/guidelines/publications/e72) (referred to hereafter as the *National Statement*). Once implemented, this document will provide evidence that an HREC has acted reasonably in reaching an opinion regarding an application for ethical approval.

The information and protocols outlined in this Operations Manual are consistent with the requirements of the *National Statement*, and all other State and Commonwealth requirements.

The Terms of Reference set out the principles of practice, and the Standard Operating Procedures detail the conduct of human research ethics activities at UNSW.

References

1. National Statement on Ethical Conduct in Human Research, National Health and Medical Research Council (NHMRC), 2007.
7. Joint NHMRC/AVCC Statement and Guidelines on Research Practice, Australian Vice-Chancellors’ Committee, the Council of Australia’s University Presidents, November 1997.
8. Australian Code for the Responsible Conduct of Research, National Health and Medical Research Council (NHMRC), Australian Research Council (ARC), Universities Australia, 2007.
12. CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).
14. UNSW policy on conflict of interest ([www.hr.unsw.edu.au/employee/conflict.html](http://www.hr.unsw.edu.au/employee/conflict.html))
Terms of Reference

OBJECTIVES

1. The objectives of the HRECs are to:

   - Protect the rights and welfare of research participants and minimise the risk of harm arising from research studies involving humans.
   - Facilitate ethical human research through efficient and effective review processes in accordance with the National Statement.
   - Promote ethical standards of human research by education of the academic community.

FUNCTIONS

2. The functions of the HRECs are to:

   Provide independent, competent, and timely ethical review of research projects involving humans.

   Ensure that research protocols comply with the principles of ethical conduct outlined in the National Statement, and all other relevant Acts and legislative requirements for that type of research.

   Determine the responsibilities, procedures and composition of the Human Research Ethics Advisory (HREA) Panels, having regard to the requirements of the National Statement; and to delegate to the HREA Panels the review of research protocols with minimal ethical impact, thereby assisting the HRECs in the performance of their role.

   Ensure that all researchers comply with the relevant guidelines on the conduct of human research, including the Australian Code for the Responsible Conduct of Research [link](http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/r39.pdf) and the UNSW Research Code of Conduct [link](http://www.gs.unsw.edu.au/policy/documents/researchcode.pdf) and other appropriate guidelines as the HRECs will deem fit.

   Conduct regular monitoring procedures to ensure that appropriate ethical standards are maintained in research projects involving humans, so as to protect the interests of the research participant, the researcher, UNSW, and the general community.

   Receive complaints, on a confidential basis, from research participants, researchers, or others on the conduct of human research projects, to deal with these in accordance with University policies and procedures, and where the content of the complaint...
constitutes a possible breach of the *UNSW Research Code of Conduct*, report them to the Designated Officer.

Protect the privacy and confidentiality of research participants by ensuring that researchers appropriately manage the security, storage and disposal of confidential data collected during the conduct of research involving humans in accordance with the UNSW Procedures for Handling Research Material and Data.

Promote awareness and understanding of human research ethics within UNSW and the broader community.

Provide advice and recommendations to the Deputy Vice-Chancellor (Research) and/or Council on any aspect of human research ethics.

Report annual to Council on the activities of the Committees via the Deputy Vice-Chancellor (Research).

**SCOPE OF RESPONSIBILITY**

3. The HRECs are responsible for:

   Reviewing, confirming ethical suitability and monitoring of research protocols involving humans where the research:
   - is carried out by any person (either alone or jointly with others) who is a full-time, part-time or conjoint staff member of the University, or a person formally recognised by the University;
   - involves human participants who are students or staff members of the University, or are otherwise connected with the University in any way;
   - is carried out using equipment, facilities or premises owned by the University or otherwise under the control of the University.

This term of reference does not prohibit the University from accepting another HREC’s ethical approval as sufficient to allow both the release of funds held by the University and commencement of the research project, provided that such other HREC is properly constituted and registered with the Australian Health Ethics Committee (AHEC).

Reviewing, confirming ethical suitability, and monitoring, of research undertaken by individuals who are not affiliated with the University, provided that an agreement exists between the University and the external researcher(s) that defines the role of the HREC in providing ethical approval and ethical monitoring of the research. The agreement will specify which party bears legal responsibility for the liabilities that arise from the ethical review conducted by the HREC, and will also specify that the researcher or his/her institution/organisation (not the University) is responsible for liabilities arising from the conduct of the research.

Education and training of UNSW researchers, as well as HREC and HREA Panel members.
STATUS OF THE HRECs WITHIN THE UNIVERSITY

4. The HRECs:

Are advisory committees of the University with responsibility to recommend that the Deputy Vice Chancellor (Research):
- grant human research approval on ethical grounds;
- withhold human research approval on ethical grounds;
- temporarily suspend human research approval on ethical grounds; and
- withdraw human research approval on ethical grounds;
for research to be carried out by staff and students of the University, or by other researchers as outlined in section 3 above.

The Deputy Vice Chancellor (Research) has authority delegated by Council to:
- give approval on behalf of the University to the conduct of ethical research;
- approve modifications to previously authorised research protocols on behalf of the University;
- temporarily suspend approval to previously authorised research protocols on behalf of the University;
- withdraw approval to previously authorised research protocols on behalf of the University.

ACCOUNTABILITY OF THE HRECs

5. The HRECs will:

Be accountable to the Deputy Vice-Chancellor (Research) and to Council in the conduct of business.

Bring to the attention of the Deputy Vice-Chancellor (Research) issues relating to human research ethics which may constitute breaches of the *UNSW Research Code of Conduct* or are otherwise deemed to be of significant concern to the University.

Make available the HRECs’ Terms of Reference, Standard Operating Procedures and membership by posting on the University website.

Provide annual reports to:
- Council via the Deputy Vice-Chancellor (Research), which will include information on: membership; the number of proposals reviewed; status of proposals; enumeration of any complaints received and their outcome; and any other information required by Council;
- the AHEC in accordance with the requirements of the NHMRC;
- The Commonwealth Privacy Commissioner in accordance with the Privacy Act, 1988;
- NSW State Privacy Commissioner in accordance with the Health Records and Information Privacy Act, 2002.
MEMBERSHIP

6. Composition:

6.1 The University will constitute one or more HRECs, sufficient to meet
the workload of applications, in accordance with the National Statement and will have a minimum membership of eight. As far as possible:
- there should be equal numbers of men and women; and
- at least one third of the members should be from
outside the institution for which the HREC is reviewing
research.

6.2 This minimum membership is:
- a Presiding Member (a chairperson), with suitable experience,
whose other responsibilities will not impair the HRECs’ capacity
to carry out
its obligations under the National Statement;
- at least two lay people, one man and one woman, who have
no affiliation with the institution and do not currently engage in
medical, scientific, legal or academic work;
- at least one person with knowledge of, and current experience
in, the professional care, counselling or treatment of people; for
example, a nurse or allied health professional;
- at least one person who performs a pastoral care role in a
community for example, an Aboriginal elder, a minister of
religion;
- at least one lawyer, where possible, one who is not engaged to
advise the institution; and
- at least two people with current research experience that is
relevant to research proposals to be considered at the meetings
they attend. These two members may be selected, according to
need, from an established pool of inducted members with
relevant expertise.

6.3 No member may be appointed in more than one of the categories
listed in paragraph 6.2, but institutions are encouraged to establish a
pool of inducted members in each category. These members may
attend meetings as needed to meet minimum HREC requirements,
and may also be available to provide expertise for the research under
review.

6.4 Wherever possible one or more of the members listed in 6.2 should
be experienced in reflecting on, and analysing, ethical decision-
making. At least two members of each Committee will have at least
two years of HREC membership experience.

6.5 The institution should ensure that the HREC has access to the
scientific expertise necessary to enable it to address the ethical issues
arising from the categories of research it is likely to consider. This may
necessitate going outside the HREC membership.

6.6 The HRECs will establish an Executive, consisting of the two Presiding
Members (or in their absence, the Deputy Presiding Members), the
Executive Officer of the HRECs.

7. Appointments:
Version 2: August, 2010
7.1 The Deputy Vice-Chancellor (Research) will appoint members of the HRECs, in consultation with the Presiding Members and other senior academic staff, as deemed appropriate.

7.2 Prospective members of the HRECs should be appointed using open and transparent processes, including recruitment by direct approach, nomination or by advertisement. Institutions should consider reviewing appointments to the HREC at least every three years.

7.3 Appointments will allow for continuity, the development of expertise within the HRECs, and the regular input of fresh perspectives.

7.4 Members will be appointed for a period of up to three years and may serve two consecutive terms only, unless otherwise approved by the Deputy Vice-Chancellor (Research). The Presiding Members may serve longer terms with the approval of the Deputy Vice-Chancellor (Research).

7.5 Members should be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organization, group or opinion. Members will be provided with a letter of appointment from the Deputy Vice-Chancellor (Research) which will include: the date of appointment; the length of tenure; an assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member; HREC meeting attendance responsibilities; and general responsibilities as a HREC member.

7.6 Reappointment will be by application to the Presiding Member of the HREC who will then make a recommendation to the Deputy Vice-Chancellor (Research).

7.7 Membership will lapse if a member fails without reasonable excuse, or without notifying the Presiding Member, to attend three consecutive meetings, or fails to attend at least five meetings of the HREC in any one year, unless exceptional circumstances exist. The Presiding Member will notify the member in writing of such lapse of membership.

7.8 A member may resign from the HREC at any time upon giving notice in writing to the Presiding Member.

7.9 The Deputy Vice-Chancellor (Research) may terminate the appointment of any member of the HREC, if the Deputy Vice-Chancellor (Research) is of the opinion that:

- it is necessary for the proper and effective functioning of the HREC;
- the person is not a fit and proper person to serve on an HREC;
- the person has failed to carry out their duties as an HREC member.

8. Conditions of appointment

8.1 Members will agree to their name and category of membership being made available to the public, including being published on the University website.

8.2 The lay and unaffiliated members as well as the Presiding Members of the HRECs will be remunerated in accordance with University policy.

8.3 Members will sign a statement undertaking that:

- all matters of which the member becomes aware during the
course of work on the HREC will be kept confidential;
- any conflicts of interest, which exist or may arise during the
  tenure of
the member on the HREC will be declared;
- the member has not been subject to any criminal
  conviction or disciplinary action for serious academic
  misconduct, which may prejudice their standing as a
HREC member.

9. Education for members

9.1 Newly appointed members will be provided with appropriate
  induction and support.
9.2 Newly appointed members will be provided with a copy of the
National Statement.
9.3 Throughout their tenure, members will be provided with equitable
  access to education sessions, conferences, workshops and training
related to technology relevant to the work and responsibilities of the
HRECs, at the expense of the University.

10. Liability coverage

10.1 The University will provide indemnity for members of the HRECs for
  any liabilities that arise as a result of the member exercising his or her
  duties as a member in good faith.

11. Procedures

11.1 The Ethics Secretariat and HRECs will perform their functions
  according to the Standard Operating Procedures.
11.2 The HRECs will be subject to regular accreditation procedures as
  outlined in the document: Accreditation Standards for the Human
Research Ethics Committees of the University of New South Wales, or
  according to other accreditation procedures as dictated by NHMRC.
  Accreditation review will be conducted periodically, such as every two
  or three years.
11.3 The Operations Manual will be reviewed periodically (approximately
  every two years) and amended and updated as necessary.
11.4 All HREC members will be provided with a copy of the Operations
  Manual and will be consulted with regard to proposed changes.
11.5 The Operations Manual, including the Standard Operating Procedures
  will be made accessible to researchers of the University by posting on
  the University website.

12. Submissions, notifications and approvals

12.1 All applications for ethical review must be submitted to the Ethics
Secretariat of the HRECs, by the relevant closing date, in the format
approved from time to time by the HRECs and will include such
documentation as the HRECs may specify.
12.2 Guidelines to assist applicants in their preparation of submissions will be made available by posting on the University website.

12.3 The Ethics Secretariat may request the applicant to supply further information in relation to an application to clarify matters prior to consideration of the submission by the HREC.

12.4 The HRECs may request the applicant to supply further information in relation to an application to clarify matters arising from their consideration of the submission.

12.5 The HRECs may request the applicant to attend a meeting of the HREC at which the application will be considered for the purpose of providing information to, and answering questions from, the HREC members.

12.6 The HRECs will consider every correctly and fully completed application which it receives at its next available meeting following receipt, provided that the application is received by the relevant closing date.

12.7 The Ethics Secretariat will circulate the completed application and associated documents received with a meeting agenda to all members of the HRECs at least 7 days prior to the next meeting.

12.8 The HRECs may delegate consideration of certain scientific/technical matters to an HREC member or sub-committee of members. The HREC may also obtain independent expert scientific/technical advice, subject to paragraph 6.5.

12.9 The HRECs may take into account the views or opinions of another properly constituted HREC in relation to a research protocol.

12.11 The HRECs will promptly notify the applicant in writing, advising whether the application which it has considered, meets the conditions of the National Statement and any conditions of that deliberation. If an application meets the requirements of the National Statement, the HREC will inform the applicant in writing that the research may commence following approval by the Deputy Vice Chancellor (Research).

13. Roles of the Executive

13.1 The HREC Executive will deal with matters as listed below (face-to-face or electronically), preferably on a weekly basis.

13.2 Where provided by the Standard Operating Procedures, the Executive will undertake expedited review of research proposals between scheduled meetings.

13.3 The Executive may opt to seek advice from other HREC members, as appropriate, before reaching a decision.

13.4 If expedited approval is granted for a new application, such approval will be considered for ratification at the next HREC meeting.

13.5 The Executive will consider other items of business such as serious adverse event reports, minor amendments and the like.

13.6 The Executive will consider changes to policies and procedures relating to human research ethics at UNSW.

13.7 Any matters arising from the Executive meeting considered to be of significance (e.g. serious adverse events) will be included on the
agenda of the next HREC meeting.

13.8 Decisions of the HREC Executive will be minuted and presented to the next meeting of the full HREC.

14. Research with minimal ethical impact

14.1 On the advice of the HREC Executive, the Deputy Vice-Chancellor (Research) will appoint members to discipline-based sub-committees to carry out timely review of research with minimal ethical impact – Human Research Ethics Advisory (HREA) Panels.

14.2 Each HREA Panel will consist of a convenor and at least two additional members of the School/Faculty/Centre with experience in the type of research activities being reviewed.

14.3 The Convenor of each HREA Panel will be appointed by Panel members.

14.4 Members of the Panels need not be members of the HRECs.

14.5 The HRECs may place a member of the Committee on any of the HREA Panels, or one or more HREC members may attend individual Panel meetings.

14.6 All applications for HREA Panel review must be submitted to the Panel administrator, by the relevant closing date, in writing in the format approved from time to time by the HREA Panel and HREC, and will include such documentation as the HREA Panel and HREC may specify.

14.7 Within the parameters set down by HREC, the HREA Panels will have autonomy in reviewing and approving applications in their own discipline area.

14.8 The HREA Panels will act in close liaison with the Heads of Schools/Centres in approving applications involving minimal ethical impact research within their discipline area.

14.9 HREA Panels will have administrative support provided by Deans of Faculties or Heads of Schools/Centres as required to carry out their activities in a timely and efficient manner.
15. Multi-centre research

15.1 To facilitate multi-centre research the HRECs may communicate with any other HREC, and accept a scientific/technical and/or ethical assessment of the research by another HREC.

16. Advocates and interpreters

16.1 The HRECs may invite an advocate for any participant or group of research participants, researchers, or an expert in a particular research methodology to the HREC meeting to ensure informed decision-making.

16.2 Where research involves the participation of persons unfamiliar with the English language, the HRECs will ensure that the Participant Information Statement and Consent Form are translated into the participant's language.

17. Meetings

17.1 The HRECs will meet on a regular basis, which will normally be at monthly intervals.

17.2 The HREC meeting dates, and the closing dates for receipt of applications will be advertised by posting on the University website.

17.3 Any member of the HREC who has a conflict of interest associated with a proposal or other related matter(s) being considered by the HREC, should as soon as practicable declare such interest. If the HREC considers the conflict to be significant and the member is present at a meeting at which the project is the subject of consideration, the member will withdraw from the meeting until the HREC’s consideration of the relevant matter has been completed. The member will not participate in the discussions and will not be entitled to vote in the decision with respect to the matter. All declarations of interest and absence of the member concerned will be minuted.

17.4 Institutional conflicts of interest may occasionally arise and should be declared by the Designated Officer at the request of the Presiding Member of the HREC. External expert reviewers will be required to declare an absence of conflicts of interest and sign a confidentiality agreement prior to their review taking place.

17.5 The HRECs will endeavor to reach a decision concerning the ethical acceptability of all applications by unanimous agreement. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority vote of two-thirds of members who examined the proposal, provided that the majority includes at least one layperson. All minority views will be recorded in the minutes.

17.6 The HRECs will provide the opportunity for investigators to meet with the Committees face-to-face if matters regarding their projects are questioned by the HRECs.

17.7 Meetings will be conducted in such a way as to encourage broad thinking as well as exchange of concepts and ideas in order to
maintain the interest and enthusiasm of the Committee and comprehensive ethical review.

18. Fees

18.1 A fee will not usually be charged for applications submitted for assessment by the HRECs from researchers who are full time, part time or conjoint appointees to the University.

18.2 A fee will be charged for applications submitted for assessment by the HREC from researchers who have no formal affiliation with the University. These researchers will also be required to sign a contract with UNSW detailing the terms and conditions under which the HREC will review the application and monitor the project.

19. Records

19.1 The Ethics Secretariat will prepare and retain written records of the HRECs’ activities, including agendas and minutes of all meetings of the HRECs and the HREC Executive which will be retained in a Minutes file in accordance with the UNSW Record Keeping Policy and the State Records Act.

19.2 The Ethics Secretariat will prepare and maintain an official university file for each application received (the Project File) including a copy of the application, and any relevant correspondence including that between the applicant and the HRECs in accordance with the UNSW Record Keeping Policy and the State Records Act.

19.3 Files will be kept securely and confidentially in accordance with the requirements of state and federal privacy legislation and the UNSW Record Keeping Policy.

19.4 Records will be held for sufficient time to allow for future reference. The minimum period for retention will be in accordance with the Australian Code for the Responsible Conduct of Research and the State Records Act, which ever is longer.

19.5 The Ethics Secretariat will maintain a database of all applications received and reviewed in accordance with the National Statement.

19.6 The Ethics Secretariat will maintain a record (the Complaints Log) of all complaints received regarding the activities of the Committee and the outcomes of those complaints, a record of all complaints received regarding research projects and the outcomes of those complaints, and a record of all possible breaches of the UNSW Research Code of Conduct which have been referred to the Deputy Vice-Chancellor (Research).

20. Post-approval responsibilities

20.1 The HRECs will monitor approved projects in terms of compliance with the HRECs’ ethical advice by requiring applicants to provide a report at least annually, and at completion of the study.

20.2 The HRECs may request information or seek discussion on any aspect of the project with the researchers at any time.
20.3 The HRECs will require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of the ethical suitability of the project, including:
- changes in the research protocol or conduct;
- serious or unexpected adverse events;
- other unforeseen events that might affect continued ethical acceptability of the project;
- if the project is abandoned for any reason.

20.4 The HRECs may adopt any additional appropriate mechanism for monitoring, as deemed necessary.

COMPLAINTS

21. Complaints concerning the conduct of a project

21.1 Complaints about the conduct of an approved HREC-reviewed project, whether from research participants, members of the public, university staff or other researchers, should be directed to the Ethics Secretariat on behalf of the Presiding Member.

21.2 If the complainant provides consent, their contact details are to be recorded in the Complaints Log held in the Ethics Secretariat so that the outcome of the investigation can be reported to the complainant.

21.3 The Executive Officer of the HRECs will notify the Presiding Members immediately after a complaint is received.

21.4 A Presiding Member of the HRECs will act in accordance with the UNSW Research Code of Conduct (refer SOP on complaints for further details).

21.5 Complaints considered as serious by the Presiding Member(s) or any potential breaches of the UNSW Research Code of Conduct will be referred immediately to the Deputy Vice-Chancellor (Research).

22. Complaints concerning the HREC’s review process

22.1 Complaints about the process of review of an application by the HRECs should be managed as per the UNSW Staff Complaint Procedure or UNSW Student Complaint Procedure. Complaints should be directed to the Director of Research Ethics Compliance and Support (RECS) through the Ethics Secretariat in the first instance.

22.2 The complaint may be referred to the Deputy Vice Chancellor (Academic) in accordance with these procedures.

AMENDMENTS TO THE OPERATIONS MANUAL

23.1 Amendments may be made to the Terms of Reference, Standard Operating Procedures and Attachments by the Ethics Secretariat, HREC Chairs, Director of Research Ethics Compliance and Support and the Office of the Deputy Vice Chancellor (Research).

23.2 This Operations Manual will be submitted for review and approval to the Deputy Vice-Chancellor (Research) following periodic review (approximately every 2 years) and in the intervening period, for any amendments deemed important by the HREC Presiding Members.