

THE AUSTRALIAN NATIONAL UNIVERSITY

TERMS OF REFERENCE

HUMAN RESEARCH ETHICS COMMITTEE

Researchers at the Australian National University (ANU) frequently conduct research involving human participants. Accordingly, the ANU maintains a Human Research Ethics Committee (HREC) that is established and continues to operate in accordance with the *2007 National Statement on Ethical Conduct in Human Research* (hereafter the *National Statement*) that has been developed by the National Health Research Council (NHMRC), the Australian Research Council (ARC) and the Australian Vice-Chancellors Committee (AVCC) and is located at:

http://www.anu.edu.au/ro/ORI/NHMRC_Human_Ethics_National_Statement_2007.pdf.

This document setting out the Terms of Reference of the ANU HREC is to be read in conjunction with Section 5 of the *National Statement* which provides further Terms with which the ANU HREC is compliant.

As emphasized in the *National Statement*, responsibility for the ethical design, review and conduct of human research is exercised at many levels within ANU, by researchers and where relevant their supervisors, by the ANU Ethics Committees and related bodies, by the ANU itself whose employees and facilities are involved in research, and by organizations responsible for funding and monitoring research.

1. DEFINITIONS

1.1 For the purposes of these Terms of Reference the following words have the following definitions:

“Primary Investigator” means the researcher or research student who is principally responsible for conducting a research project.

“Ethics Committee” means either the HREC or a DERC as the context requires.

“Human Research” means any investigation with or about people or their data or tissue, where such investigation is undertaken to gain knowledge and understanding. It does not include routine testing and analysis, quality control, and the development of teaching materials.

“Researchers” includes **Primary Investigators, co-investigators, and research students** with the latter including undergraduate (Honours) students and higher degree by research students.

2. RESEARCH THAT CAN BE EXEMPTED FROM REVIEW

2.1 Research is exempt from ethical review if it is:

(a) Negligible risk research, which is defined as research where there is no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenience; and

(b) Involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

3. CONSULTANCIES AND HUMAN RESEARCH ETHICS APPROVAL

University consultancies may involve activities that fall within the definition of human research. All such activities are subject to ethical review under the terms of this document. The source of funding – be it consultancy, grant or internal – does not determine whether or not ethical review is required.

4 ROLES OF THE HREC

4.1 To review proposed research projects involving human subjects that fall within the jurisdiction of the ANU, and to approve research projects that meet the requirements of the *National Statement* and are ethically acceptable.

The ANU and HREC has jurisdiction over the research of all ANU Researchers (paid and honorary) and research students, and all academic visiting Researchers to ANU including those using ANU facilities.

ANU education activities do not normally require ethical approval. It is expected that all ANU education activities will be conducted in accordance with the requirements of the *National Statement*.

4.2 To foster awareness and concern among ANU researchers and supervisors for all dimensions of ethical practice in Human Research, including oversight of training programs conducted by, or for, the Office of Research Integrity.

4.3 To advise the Vice-Chancellor and any other appropriate ANU officer on any aspect of research involving human subjects that falls within the jurisdiction of the Australian National University. The advice will, in particular, cover policies and practices for the review, approval, monitoring and administration of such Research.

5 DELEGATION OF ETHICAL REVIEW

5.1 The HREC will delegate the review and approval of certain low-risk research projects (designated “Expedited Review Category 1: E1”) to the Chairperson and/or Deputy Chairpersons of the HREC as permitted by the *National Statement*.

5.2 The HREC will delegate the review and approval of certain low-risk Research projects (designated “Expedited Review Category 2: E2”) to a Delegated Ethical Review Committee (DERC) as permitted by the *National Statement*.

5.3 The delegates under sections 5.1 and 5.2 must refer to the HREC any research that it considers involves more than low risk.

5.4 Following review of a research proposal by the relevant Ethics Committee, delegation of subsequent functions may be given to the Chairperson of the relevant Ethics Committee,

including the approval of an amended research proposal following negotiations with researchers.

6 OFFICE OF RESEACH INTEGRITY

- 6.1 The ANU will administer the ethical review and reporting of Human Research through the ANU Office of Research Integrity.
- 6.2 The Office of Research Integrity provides resources and services to the Ethics Committees and ANU researchers to support the requirement of sound ethical review, and to communicate and train ANU researchers.
- 6.3 The Director of the Office of Research Integrity (“Director”) will assign a secretary (“Secretary”) for each Ethics Committee. The duties of each secretary will be to administer the Committee process and to minute meetings. Ethics Officers (“Ethics Officer”) working within the Office of Research Integrity, whose primary role is the administration or research ethics, will normally fill this role.

7 COMPOSITION OF MEMBERSHIP OF ETHICS COMMITTEES.

- 7.1 The ANU HREC is constituted according to the requirements of the *National Statement* and comprises:
 - 7.1.1 A Chairperson;
 - 7.1.2 Two members who are lay people, one man and one woman, who have no affiliation with the Australian National University, and who are not involved currently in medical, scientific, academic or legal work;
 - 7.1.3 One member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
 - 7.1.4 One member who is a minister of religion, or a person who performs a similar role in a community, such as an Aboriginal elder;
 - 7.1.5 One member who is a lawyer but is not employed to provide advice to the ANU;
 - 7.1.6 One member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC.
- 7.2 A DERC comprises:
 - 7.2.1 A Chairperson, normally the Chairperson or a Deputy Chairperson of the HREC; The Chairperson, and one or more Deputy Chairpersons are appointed by the Vice-Chancellor.
 - 7.2.2 Three members with knowledge of, and current experience in, the areas of Research that are regularly considered by the DERC.
- 7.3 The Chairperson of an Ethics Committee has the power to seek additional advice as required by the Committee, and may invite an advisor(s) to attend and have a voice in meetings of the

Committee.

8 CONDITIONS OF APPOINTMENT TO ETHICS COMMITTEES

- 8.1 Appointments to an Ethics Committee will be made by the Deputy Vice-Chancellor.
- 8.2 Appointments to the HREC shall be normally for a period of two (2) years, and may be renewed for a further period.
- 8.3 Appointments to a DERC shall normally be for a period of one (1) year, and may be renewed for a further period.
- 8.4 The Chairperson of an Ethics Committee is appointed by the Deputy Vice-Chancellor, unless the Chairperson is the Deputy Vice-Chancellor who is appointed by the Vice-Chancellor.
- 8.5 Members will be advised in writing of their appointment to an Ethics Committee and the conditions of their appointment.
- 8.6 The Australian National University will provide legal protection for all Ethics Committee members, in respect of liability that may arise in the course of the *bona fide* conduct of their duties as members.
- 8.7 A person's membership of an Ethics Committee may be withdrawn by the University at any time during the period of appointment. Any such decision will be advised in writing where possible.

9 MEETINGS

- 9.1 Meetings of Ethics Committees will be held at dates and times to be determined by the HREC. Meeting dates will normally be set by the end of each calendar year for the ensuing 12 month period. The meeting dates will be published on the Human Ethics homepage.
- 9.2 The Chairperson may call additional meetings of the HREC, should a situation call for such additional meetings, provided that 14 days notice is given to the Committee members.
- 9.3 The Chairperson of a DERC may call additional meetings should a situation call for such additional meetings, provided that 5 days notice is given to the Committee members.
- 9.4 All matters relating to protocols and Ethics Committee proceedings are confidential. Copies of all current protocols will be kept in the Office of Research Integrity.
- 9.5 All Ethics Committee papers are to be disposed of through a confidential recycling bin.
- 9.6 An Ethics Committee should endeavour to reach decisions by general agreement. Failure to agree may require an extension of time to reconsider the research protocol and its possible amendment, especially when any member is not satisfied that the welfare and rights of participants are protected.

- 9.7 No Ethics Committee member shall adjudicate on research in which that member has any conflict of interest including any personal involvement or participation in the research, any financial affiliation or interest in the outcome, or any involvement in competing research. A member of the supervisory panel for a research student whose protocol is under consideration shall absent themselves from the meeting while that protocol is under discussion.

10 PRESENTATION OF RESEARCH PROPOSALS

- 10.1 All applications for research to be considered by an Ethics Committee must be submitted by the Primary Investigator electronically using the ANU on-line *Human Research Ethics Application Form* provided in the ANU Research Information Enterprise System (ARIES).
- 10.2 No fees are charged for consideration of research proposals from the ANU staff or Research Students.
- 10.3 The National Statement allows for non-ANU affiliated researchers who do not have access to an institutional HREC, to submit an application through the ANU HREC processes. This is subject to the agreement of the ANU HREC Chairperson. An administration fee may be charged for the review and approval of Research proposals by non-ANU staff, at a level to be fixed from time to time by the Deputy Vice-Chancellor.

11 WORKING PROCEDURES

- 11.1 The HREC will normally meet on a monthly basis. Unless otherwise approved by the Chairperson, all research proposals for HREC approval must be submitted by close of business on the first working day of the month in order to be considered at the Committee meeting during that month. The dates for submission of all research proposals will be published on the Human Ethics homepage.
- 11.2 A DERC will normally meet on a fortnightly basis. Unless otherwise approved by the Chairperson, all research proposals for DERC approval must be submitted by close of business 10 working days prior to the Committee meeting date in order to be considered at that meeting. The dates for submission of all research proposals will be published on the Human Ethics homepage.
- 11.3 Ethics Committee members will receive meeting papers not less than seven days prior to the relevant meeting date.
- 11.4 The Primary Investigator will normally be advised of the outcome of the Ethics Committee's review of their research proposal within two weeks of the Ethics Committee meeting. However, the review process may be extended where the Ethics Committee's review of a research proposal entails preliminary feedback being given to the Primary Investigator, which may include questions, suggestions and requirements.
- 11.5 The Chairperson of the Ethics Committee will normally consider the responses of the Primary Investigator to these questions, suggestions and requirements shortly after they have been submitted. The Chairperson may refer the response to the full Committee or the Primary Investigator may be invited to meet with the Committee to try to resolve difficult

issues.

- 11.6 Notification of approved research proposals will include instructions in relation to length of approval, compliance, reporting, monitoring of adverse outcomes and complaints procedures.
- 11.7 No research may commence until the Primary Investigator has received formal notification of approval from the Office of Research Integrity.
- 11.8 Notification of approval will be provided electronically by the ARIES Human Research Ethics system.
- 11.9 The HREC will report annually to the ANU Council and the National Health and Medical Research Council, and as otherwise required. The report to ANU Council details operations, membership, development and training activities, future goals, and relevant statistics. The NH&MRC require the completion of an annual compliance report.

12 RECORDING OF DECISIONS

- 12.1 The ANU shall retain on file a copy of each Research protocol and research proposal, including, information sheets, consent forms and/or correspondence in the form in which they are approved.
- 12.2 With the exception of the signed application, all records are maintained electronically within ARIES.

13 MONITORING

- 13.1 The Primary Investigator must annually provide the HREC Secretary with a written report using the on-line form provided in the ANU Research Information Enterprise System (ARIES). The object of the report is to verify that the conduct of research confirms to the approved process.
- 13.2 The HREC may adopt any additional procedures for monitoring research that it considers appropriate.
- 13.3 Primary Investigators must immediately report to an Ethics Officer any other changes or events that may warrant review of the ethical approval for their research proposal including proposed changes to the protocol and/or unforeseen events.

14 COMPLAINTS PROCEDURES

Complaints from Researchers

- 14.1 Consistently with the National Statement, the ANU provides for complaints about the process of ethical review, but does not provide for an appeal against a final decision to reject a proposal.
- 14.2 If an application is being considered for rejection, it must be reviewed the HREC, and the Researcher/s must have had an opportunity to address the HREC's concerns at an interview.

The decision by the HREC to reject an application is final and may not be appealed.

- 14.3 Complaints about the process of ethical review must be made in writing to the Director of the Office of Research Integrity, who will inform the Chairperson of the HREC of the complaint, and investigate and attempt to resolve the matter. Researchers have the right to attend one meeting of the HREC to present their complaint in person.

Complaints from research participants

- 14.4 Complaints by research participants will be made normally to the Primary Investigator or to the Ethics Officers. Researchers who receive a complaint from a research participant must notify the Ethics Officer as soon as possible. The Ethics Officer will advise the Director of the Office of Research Integrity and Chairperson of the relevant Ethics Committee of the complaint at the earliest opportunity.

- 14.5 The Chairperson will consider the complaint and will take what action he/she deems appropriate, as soon as possible. This action may include nominating the Director of the Office of Research Integrity to have a direct discussion with the relevant research participant and/or direct contact with the Primary Investigator. The process will usually involve verification that the protocol approved by the Committee has been followed and subsequent action may include temporary withholding of ethics approval. All discussions will be conducted in a confidential manner.

Complaints from other parties

- 14.6 Any complaint from other interested parties will be managed normally according to the procedure set out in section 14.4 above 'Complaints from research participants'.

15 SUSPENSION OR DISCONTINUATION OF RESEARCH

- 15.1 If an Ethics Committee is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol and that, as a result, the welfare and rights of the research participants are not, and will not be protected, the Committee may withdraw approval, inform the Primary Investigator of such withdrawal, and advise that the research project has been discontinued, suspended or other steps be undertaken.

Date issued: