HUMAN RESEARCH ETHICS COMMITTEE
WORKING PROCEDURES

1. APPOINTMENT OF MEMBERS

Membership of the Human Research Ethics Committee is specified in the *Terms of Reference*.

All members of the Committee, including alternates, will be appointed by the Vice Chancellor or the Deputy Vice Chancellor Research.

New members will receive a formal notice of appointment which includes:

- specification of the category of membership to which the person is appointed;
- notification that the term of membership is two years and may be renewed;
- a statement that the University accepts legal responsibility for decisions and advice received from the Committee, and indemnifies members for any action taken against them in respect of Committee business;
- reference to the requirement in the *National Statement on Ethical Conduct in Human Research* that all members be fully informed and have an opportunity to contribute their views on each application considered by the Committee; and
- information on the Committee and its operations, including the Committee Terms of Reference, Working Procedures, Assessor Handbook, and a copy of the *National Statement*.

Upon appointment to the Committee, members will also be required to sign a Confidentiality Agreement.

The Research Ethics & Integrity Unit will advise the University's insurance consultant of changes in membership as they occur, and supply personal details/curriculum vitae of new external members of the Committee as required.

2. APPOINTMENT OF NON-COMMITTEE ASSESSORS

The *National Statement* allows for institutions to establish non-HREC levels of ethical review for low risk research. A pool of Faculty/University Research Centre-based Human Research Ethics Assessors may be appointed to assist with the evaluation of low-risk applications. Although they will not be required to attend Committee meetings, they will be expected to provide written reports by the stipulated deadlines, with their reports to be tabled at the Committee meetings.

3. FREQUENCY OF MEETINGS AND COMMITTEE SCHEDULE

The Committee will meet at least 10 times a year.

In determining meeting frequency, the Committee will take into account the need of academic staff and students for timely consideration of research proposals.

Meeting dates will be widely publicised within the University community.

To assist researchers with their planning, a proposed schedule for the following year will be published in the latter part of the year. The schedule will include closing dates for submission of applications (approximately two weeks before the meeting) and meeting dates.

Meeting and closing dates should be announced to staff and advertised on the Research Services website.

4. PREPARATION OF AGENDAS, MINUTES AND COMMITTEE RECORD KEEPING

4.1 Committee database

The Research Ethics & Integrity Unit will record details of each application to conduct research with human participants on the Committee database. Information on the database will include:

- Project identification number;
- Meeting number(s) at which application considered;
- Name and contact details of principal researcher;
- Name and contact details of supervisor, if applicable;
- Faculty/University Research Centre of applicant/supervisor;
- Title of project;
- Starting date and anticipated completion date for the project;
- Names of two committee members assigned by the Chair to assess each application before the meeting;
- Relevance of the Privacy Act 1988;
- Date of approval;
- Committee decision;
- Committee evaluation;
- Committee comment, if applicable;
- Details of Committee monitoring activity, including dates on which project review forms are sent out by the Research Ethics & Integrity Unit and returned by researchers;
- Other details as required

4.2 Agenda

Following the closing date for submission of applications for approval, the Research Ethics & Integrity Unit will prepare an agenda for the meeting in consultation with the Chair.

The Agenda will include:

- Apologies;
- Minutes of the previous meeting, including details of the Committee's evaluation of and decision on each application considered at the meeting;
- Matters arising from the Minutes, including a report on the status of applications considered at the previous meeting and incomplete applications from earlier meetings in the current year;
- A list of applications to be considered at the meeting, generated from the database. The list will identify assessors selected by the Chair or Research Ethics & Integrity Unit to evaluate each application in advance of the meeting as well as the application's risk level, as determined by the Chair.
- Periodic reports on the monitoring of approved research projects;
- Other matters for Committee discussion;
- Information items;
- Provision for members to raise Other Business; and
- Details of the following Committee meeting.

4.3 Meeting report and minutes

After the meeting, the Research Ethics & Integrity Unit will record the Committee decision in the database and draft the evaluation and comments on each application. The Chair will approve the wording of the evaluation before letters are sent to applicants.

The Research Ethics & Integrity Unit will prepare Minutes of the meeting for approval at the next meeting.

5. DISTRIBUTION OF MEETING PAPERS TO COMMITTEE MEMBERS

Meeting papers, including copies of all applications to be considered, will normally be distributed to members one week before the meeting in electronic form, unless otherwise specified.

Committee papers are confidential, and should be held and taken care of by members in ways which protect their confidentiality. If members print or receive a printed set of papers then those papers should be returned to the Research Ethics & Integrity Unit for disposal via confidential waste when members have finished with them.

All papers associated with each application, including questionnaires, correspondence and other supporting materials, will be provided to all Committee members. Assessors' report forms will be provided to the Committee members allocated to assess each application before the meeting.

6. COMMITTEE GUIDANCE TO APPLICANTS

The Committee will assist applicants to meet Committee requirements by publishing explanatory material, including the *Human Ethics Manual*. The Manual, which should be reviewed each year, will include such information as:

- reference to and information on the National Statement
- guidelines to assist researcher to know when ethical approval is required
- details on making an application, including closing dates for receipt of applications and meeting dates for the year
- responsibilities of staff
- reference to the University of Canberra *Responsible Conduct of Research Policy*
- guidelines for composing an Informed Consent statement
- information on the Information Privacy Principles and applying the Privacy Guidelines.

7. TIMELY CONSIDERATION AND REVIEW OF RESEARCH PROPOSALS

New applications will be considered only at scheduled meetings of the Committee.

All applications, including resubmitted applications, received by the Research Ethics & Integrity Unit before or on the due date will be considered at the meeting immediately following that date, provided that they are complete and include all requisite signatures.

Where the Committee has determined that amended applications require reassessment, the Research Ethics & Integrity Unit will arrange this within two weeks following receipt of the revised application.

Low risk applications may only be assessed out of session on request and only if there are relevant reasons for this request (i.e. timing of research, grant application requirements etc.). An out of session request should be sent to the Research Ethics & Integrity Unit for consideration. High risk applications can only be considered at a scheduled meeting.

8. COMMITTEE DECISION MAKING

8.1 Involvement of all members

As required by the *National Statement*, all members will be fully informed by receipt of all relevant papers and will have an opportunity to contribute their views in the decision-making process on each application.

Members who are unable to attend a meeting may submit written comments, and/or completed Assessors Report forms, to the Research Ethics & Integrity Unit before the meeting. The Research Ethics & Integrity Unit will ensure that comments from absent members are read and discussed at the meeting.

If members of the Committee are absent from a meeting, the Chair must be satisfied, before a decision is reached, that the minimum membership (categories 1 to 6 and at least one member in category 7 of membership in the Committee Terms of Reference) has received all papers and

had an opportunity to contribute their views, and that these views have been recorded and considered.

8.2 Conflicts of interest

Members must declare any real or potential conflict of interest. No member of the Committee shall adjudicate on research in which that member has an interest, including personal involvement, financial interest or involvement in competing research.

A member of the Committee who is the principal researcher on a proposal being considered by the Committee should leave the meeting during discussion and decision-making on his/her application.

A member of the Committee who is supervisor of a project under consideration may be present for discussion, unless the Committee determines otherwise.

8.3 Availability of applicants during meetings

In exceptional circumstances, the Committee may invite an applicant and/or the applicant's supervisor to be available to provide advice or clarification during a meeting, or to be present at the meeting for discussion of an application.

8.4 Use of advice or assistance from non-HREC members

In exceptional circumstances, the Committee may seek advice from experts to assist with consideration of a research proposal, provided that such experts have no conflicts of interest in relation to the proposal under consideration. In addition, for the evaluation of low-risk applications, the Committee may call upon non-HREC Assessors (see section 2 above) as needed.

8.5 Committee evaluation and decision

The Committee will evaluate each application using the following categories:

- **Approved with no changes**
  The project may proceed as submitted.
- **Pending approval -minor or major changes**
  The project may proceed subject to specified minor revisions. However, before the project can proceed, the applicant must provide amended sections of the application and any further documentation to the Research Ethics & Integrity Unit, who will check to ensure that requested changes have been made.
- **Not approved - Chair to reconsider**
  The application must respond to specified matters raised by the Committee and provide amended and/or further documentation to the Research Ethics & Integrity Unit for reassessment of the proposal by the Chair. The Chair will evaluate the application according to the range of categories listed in this section.

- **Not approved - Resubmit**
  The applicant must address major issues raised and resubmit the application to the Committee at a subsequent meeting.
- **Not approved**
  If the Committee assesses a proposal as completely unacceptable, it may reject the application without offering the applicant the option of resubmitting a revised proposal.
- **Approval not required**
  The research proposal does not require approval by the Committee.

In all cases the Committee will provide applicants with the reasons for its decision.

The Committee may also provide comments and advice to applicants.

8.6 Dates and period of approval

For applications approved at a meeting, the date of approval will be the date of the meeting or the date of the letter notifying the applicant of the approval. For applications approved subsequent to the meeting at which they were considered, the date of approval will be the date of the letter notifying the applicant of the approval.

The Committee will normally grant approval for the period of time between the starting and anticipated completion dates of the project stated on the application form.

The Committee cannot grant retrospective approval. If the starting date nominated by the applicant precedes the date of approval, the approval period will begin on the date at which the project was approved.

The maximum period of approval to be granted by the Committee will be three years.

Academic staff who, as part of their teaching, undertake the same project or experiment each year with a different group of students, may apply for approval for up to three years. The Committee may grant approval for that length of time on condition that the member of staff:

- provides a full application for the first year, stating the maximum period for which approval is sought;
- submits a letter each subsequent year to confirm that the research protocol remains the same (any changes must be notified to the Research Ethics & Integrity Unit for consideration by the Chair, who may approve the changes or refer them to the Committee), together with a copy of the Informed Consent Statement for that year; and
- returns a project review form each year.

Application to alter or extend a period of approval must be made in writing to the Research Ethics & Integrity Unit. Requests for extension should:

- be submitted before current approval expires;
- specify a new completion date;
- provide reasons for the request; and
- be endorsed by the project supervisor, if applicable.

The Research Ethics & Integrity Unit may approve the request or require the researcher to apply to the Committee.

9. AUTHORITY OF THE CHAIR

The Chair of the Committee may:

- consider research proposals and advise researchers on whether a project requires Committee approval;
- reconsider and, if appropriate, approve amended applications after initial consideration by the Committee, when authorised to do so by the Committee;
- consider and authorise minor amendments to approved projects, including amendments or extensions to periods of approval;
- at the request of an applicant or supervisor, provide clarification and/or further information on the Committee's evaluation of an application;
- consider and endorse project review forms;
- act as the initial point of reference for complaints about Committee process and, if necessary, refer complainants to University procedures for dealing with complaints about research;
- approve changes to Committee procedure in special circumstances, within the framework of the requirements of the *National Statement*;
- provide advice to staff and students on Committee functions and on ethical issues in research;
- perform other tasks as delegated by the University Research Committee; and
- delegate some or all of the responsibilities in this section to the Deputy Chair.

10. PROMPT NOTIFICATION OF DECISIONS

The Committee will provide each applicant (and the research supervisor where applicable) and his/her faculty's Associate Dean Research with a written evaluation which includes the decision and the reasons for that decision. Notifications will normally be sent to applicants within one week of the meeting at which the application was considered.

Applicants may seek verbal advice on the Committee's evaluation from the Research Ethics & Integrity Unit in advance of the formal notification. However, such advice may not always be available and is always subject to written confirmation.
When approval is granted, the Research Ethics & Integrity Unit will supply an official approval letter outlining the title of the research, approval date, end date and any restrictions and/or requirements.

Applicants may seek further information or clarification of Committee decisions from the Research Ethics & Integrity Unit.

Amendments to applications will normally be considered, and the decision made available to the applicant, within a week of receipt of the amended application by the Research Ethics & Integrity Unit.

11. REPORTING OF PROPOSED CHANGES IN PROTOCOL AND ADVERSE EVENTS

Researchers must adhere to the protocol approved by the Committee. If changes are proposed, the researcher must provide details in writing to the Research Ethics & Integrity Unit. Minor changes may be approved out of session or if appropriate referred to the Chair or full Committee for approval. .

Researchers must immediately advise the Committee of adverse events. In accordance with the *National Statement*, notifications of approval to applicants will include the following:

> *You must immediately report to the Committee anything which might warrant review of ethical approval of your project, including:*
> - *serious or unexpected adverse effects on participants;*
> - *proposed changes in the protocol; and*
> - *unforeseen events that might affect continued ethical acceptability of the project.*

12. APPROPRIATE MONITORING OF RESEARCH

12.1 Responsibility of the Committee, researchers and supervisors

The Committee is responsible for monitoring research for which it has given approval.

At regular periods, no less frequently than annually, the Research Ethics & Integrity Unit will request reports from researchers on:

- progress to date or outcome in the case of completed research;
- maintenance and security of records;
- compliance with the approved protocol; and
- compliance with any conditions of approval.

In signing the Declaration on the application form for approval, applicants undertake to assist the Committee to monitor the conduct of research by completing and promptly returning project review forms, which will be sent to researchers annually and/or at the completion of the project, as appropriate. Where the applicant is a student, the supervisor undertakes to ensure that project reports are submitted to the Committee as required.

If a principal researcher who is a student cannot be contacted or fails to return a project review form, the supervisor is responsible for completing and returning the form on the researcher's behalf.

The Committee may recommend and/or adopt additional mechanisms for monitoring at its discretion.

12.2 Project reviews

Reports from researchers are collected on a Committee form entitled *Review of Research Projects Involving Human Participants* completed by the researcher, and signed by the researcher and, where applicable, the supervisor. As stated above, if a student researcher fails to return a form, the form will be sent to the supervisor for completion.

The Research Ethics & Integrity Unit will ensure that returned review forms are checked and any issues tabled at Committee meetings.

At least once each semester, a list of projects for which review forms have been received, identifying completed and continuing projects, will be provided to the Committee. The Chair may refer to the Committee issues arising from answers to questions on the review form.

13. RECEIVING COMPLAINTS

13.1 Complaints about an approved project

Concerns about the conduct of approved research projects may be raised by anyone, including potential participants or participants in the research, other members of the University, members of the general community, the researcher or the research supervisor.

Concerns and inquiries about student research projects conducted as part of the requirements for undergraduate or coursework degrees should be raised in the first instance with the research supervisor. Contact details for the project supervisor are provided to all participants in supervised research.

Concerns about research conducted by staff or by students undertaking research degrees should be raised in the first instance with the principal researcher. In projects for higher degrees by research, the research supervisor provides a secondary point of reference.

If discussions with the researcher and/or research supervisor do not resolve the problem to the complainant's satisfaction, the complaint should be lodged in writing to the Research Ethics & Integrity Unit.

In accordance with the National Statement, contact details for the Research Ethics & Integrity Unit as the recipient of complaints will be provided to all participants in research involving human participants.

13.2 Complaints about Committee process

Concerns from applicants or supervisors about the consideration of research applications by the Committee, or other aspects of Committee business, should be raised in the first instance with the Research Ethics & Integrity Unit and applicants may be referred to the Chair in certain circumstances. If discussions with the Research Ethics & Integrity Unit and/or the Chair do not resolve the matter to the applicant's satisfaction, the complainant will be advised to follow formal University complaints procedures.

13.3 Allegations of Misconduct in Research

The *Procedures for Dealing with Allegations of Misconduct in Research* are contained within the *[Responsible Conduct of Research Policy](#)*. They specify responsibilities for dealing with allegations of research misconduct and specify that such allegations must be submitted in writing to the Designated Complaints Receiver, who will follow appropriate procedures.

The University has appointed *[Advisers on Integrity in Research](#)* to guide UC staff and students who have may concerns about research conduct issues. This could include providing assistance in the interpretation of misconduct in research as detailed in the UC *[Responsible Conduct of Research Policy](#)* as well as the *[Australian Code for the Responsible Conduct of Research](#)*, providing confidential advice in instances where staff or students/trainees are considering reporting research misconduct, and explaining options available in the event that an allegation of misconduct is to be pursued. The Advisers are not faculty or research centre specific, and staff and students are free to consult any of the Advisers. Serious concerns about possible research misconduct should, in the first instance, be raised with an Adviser on Integrity in Research.

14. ADVISING THAT A RESEARCH PROJECT BE DISCONTINUED

If a complaint is found to be justified, and/or for any reason the Committee is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in a way which minimises risk and protects the welfare of participants, the Committee may:

- withdraw approval;
- inform the researcher and the Associate Dean Research of such withdrawal; and
- recommend to the appropriate authority that the research project be suspended or discontinued.

A researcher must not continue research if ethical approval has been withdrawn.

15. FEES TO BE CHARGED

The Committee will not charge fees for the assessment of applications.

16. CONFIDENTIALITY OF THE CONTENT OF PROTOCOLS AND OF COMMITTEE PROCEEDINGS

Deliberations of the Committee are confidential.

The Committee will not release information on the content of research protocols.

Individual Committee members may be available to advise applicants on research proposals before submission to the Committee. However, Committee members will not disclose the Committee's deliberations to an applicant or to anyone else, unless specifically authorised to do so by the Committee.

The Research Ethics & Integrity Unit will communicate Committee decisions in writing to the researcher and, if applicable, the research supervisor. Unless otherwise agreed by all parties involved, details of the evaluation will be made available only to the researcher, the research supervisor and the Associate Dean Research.

Applicants who seek further information on the Committees decision or evaluation should contact the Research Ethics & Integrity Unit, who may refer the applicant to the Chair.

17. MAINTAINING UNIVERSITY AWARENESS OF ETHICAL REQUIREMENTS

In accordance with the *Terms of Reference*, the Committee is responsible for raising and maintaining awareness in the University community of ethical issues in research involving human participants, the rationale for ethics approval, University requirements and the ethics approval process.

Activities the Committee may undertake to fulfill this responsibility include:

- regular publicity on the Committee's work, eg staff announcements, notices or articles in *Monitor*;
- contact with research supervisors, individually or in groups;
- involvement in induction programs for research students;
- talks to class groups at the invitation of academic staff;
- seminars or workshops organised by the Committee;
- visits by the Chair or Committee members to Faculty/University Research Centre Forums and/or Research Committees; and
- other action as appropriate.

18. COMMITTEE REPORTING

The Committee will provide an annual compliance report to the National Health and Medical Research Council on matters specified in the *National Statement*. The Committee will provide other information to the NHMRC on request.

The Committee will report annually to the University Research Committee, Academic Board, Vice Chancellor and to Council.

Information in the University report will include:

- number of Committee meetings held during the year;
- details of membership changes, and Committee membership during the reporting period; and
- a list of research projects considered, and statistics on:
  - ➢ total number of applications
  - ➢ breakdown by discipline/discipline group
  - ➢ breakdown by Faculty/URC
  - ➢ Committee decision on each application (as initially presented and whether finally approved); and
- a summary of other Committee activities.

19. AMENDMENT OF WORKING PROCEDURES

Changes to this document must be approved by the Committee, and must not affect compliance with the *National Statement*. The Research Ethics & Integrity Unit will maintain records of amendments and the date of each amendment.