

HUMAN RESEARCH ETHICS MANUAL

Section 1 Introduction and Overview

All University research activity is governed by the [National Statement on Ethical Conduct in Human Research](#), the [Australian Code for Responsible Conduct of Research](#) and the [Commonwealth Privacy Act 1988](#) and relevant University of Canberra policies.

Members of the University community at the University of Canberra who intend to conduct research with human participants must apply to the Human Research Ethics Committee for approval and must also ensure their project is conducted in accordance with the National Guidelines.

1.1 Introduction

This Manual provides information to help researchers decide when an application is necessary and to guide applicants through the approval process. It is important for staff members who supervise student research projects involving human participants, as well as staff and student researchers, to become familiar with universities requirements outlined in this publication.

Section 2 National Guidelines

2.1 The National Statement on Ethical Conduct in Human Research

2.1.1 Background

The Human Research Ethics Committee was established and functions under guidelines issued by the National Health and Medical Research Council in accordance with the [NHMRC Act 1992](#) (Commonwealth). The guidelines are contained in a comprehensive national statement of research ethics entitled the [National Statement on Ethical Conduct in Human Research](#). The *National Statement* is an essential reference for researchers in all disciplines involving humans.

The relationship between researchers and research participants is the ground on which human research is conducted. Values and principles - as set out in the National Statement - including respect for human beings, research merit and integrity, justice, and beneficence, help to shape that relationship as one of trust, mutual responsibility and ethical equality. (Refer to Section 1 of the *National Statement*).

2.1.2 Contents of the National Statement

Briefly, the *National Statement* encompasses the following:

- Values and principles of ethical conduct;
- Themes in research ethics: risk and benefit, consent;
- Ethical considerations specific to research methods or fields;
- Ethical consideration specific to participants;
- Processes of research governance and ethical review

The section on Ethical Considerations Specific to Research Methods or Fields covers:

- Qualitative methods;
- Databanks;
- Interventions and therapies, including clinical and non-clinical trials and innovations;
- Human tissue samples;
- Human Genetics;
- Human stem cells.

The section on Ethical Consideration Specific to Participants covers:

- Women who are pregnant and the human foetus;
- Children and young people;
- People in dependent or unequal relationships;
- People highly dependent on medical care who may be unable to give consent;
- People with a cognitive impairment, an intellectual disability, or mental illness;
- People who may be involved in illegal activities;
- Aboriginal and Torres Strait Islander peoples;
- People in other countries.

2.1.3 Human Research Ethics Committees

The [*National Statement*](#) guidelines for research proposals involving human participants to be reviewed and approved by a Human Research Ethics Committee (HREC). The primary role of an HREC is to protect the welfare and the rights of participants in research.

HRECs must follow guidelines outlined in the *National Statement* in regard to their composition, appointment of members and many aspects of their operational procedures. Committee Terms of Reference and Working Procedures must be documented. Other requirements for HRECs of particular interest to users of this Manual are:

- Records must be kept of all research protocols received and reviewed.
- All core members of the HREC must have the opportunity to be involved in decision making on all applications considered by the Committee.
- Approved research projects must be monitored by mechanisms including, as a minimum, regular reports from researchers on progress and outcomes of research and compliance with the approved protocol.
- Institutions with HRECs must establish procedures for dealing with complaints about the conduct of approved research projects and provide information on these procedures to all participants in the research.
- HRECs must report annually to the NHMRC through its principal committee, The Australian Health Ethics Committee.

Some of these requirements are explained in greater detail in later sections of this Manual.

2.2 Guidelines on privacy of information

Researchers should become familiar with the Information Privacy Principles which are contained in the [Commonwealth Privacy Act 1988](#), to which the University must comply.

2.2.1 Information Privacy Principles and the Privacy Act

The Information Privacy Principles (IPPs) relate to the collection, management, storage and disclosure of personal information by Commonwealth agencies. The IPPs may be found in Section 14 of the [Commonwealth Privacy Act 1988](#).

Other sections of the *Privacy Act* that may be helpful to applicants are:

- Section 6 Interpretation, which defines terms such as agency, Commonwealth enactment, personal information and record;
- Section 15 on Application of IPPs; and
- Section 95 on Medical Research Guidelines.

2.2.2 Section 95 Privacy Guidelines

Section 95 of the *Privacy Act* empowers the NHMRC to issue guidelines for the protection of privacy in the conduct of medical research. The purpose of the guidelines is to ensure that personal information is protected against unauthorised collection or disclosure. These guidelines, also referred to as the Section 95 Privacy Guidelines, are contained within the NHMRC publication [Guidelines approved under section 95A of the Privacy Act 1988](#).

A flow chart to assist researchers to know when the Privacy Guidelines should be applied is available on page five of the [Guidelines approved under section 95A of the Privacy Act 1988](#).

Researchers will note that the *Section 95 Privacy guidelines* apply only to medical research (including epidemiological research) involving personal information obtained from Commonwealth agencies. However, it is recommended that the *Section 95 Privacy Guidelines* be applied to all research involving the use of personal

information. The Commonwealth Privacy Commissioner has sought information from the NHMRC, which in turn is seeking information from Human Research Ethics Committees on an annual basis, on use of the guidelines where personal information is obtained from sources other than the individuals themselves or a Commonwealth organisation. Examples of such restricted information (ie existing records which identify individuals, but which are not normally available to the public) would include:

- Medical records (owned by a public or private hospital or medical practitioner);
- Records from State-based registers (eg cancer registers, genetic registers); and
- Records from State department (e.g. health, corrective services, education).

Section 3 UC Human Research Ethics Committee

3.1 Role

According to its *Terms of Reference*, the role of the UC Human Research Ethics Committee (HREC) is to:

- i. develop and administer an approval process and maintain a register of applications for approval to conduct research, including certain teaching-related research activities, with human participants, in accordance with the *National Statement*;
- ii. assess applications, offer guidance to the applicant if changes are required and approve or reject the application;
- iii. monitor the progress of research approved by the Committee by requiring, at least annually, reports from principal researchers on matters specified in the *National Statement*;
- iv. raise and maintain awareness, including through the oversight of appropriate training programs, in the University community of ethical issues in research involving human participants, the rationale for ethics approval, University requirements and the ethics approval process;
- v. liaise as appropriate with the University Research Committee or other committees of the University as required;
- vi. remain informed on NHMRC ethical guidelines and, where possible, developments and new requirements through publications, journals and conferences; will
- vii. provide an annual compliance report to the NHMRC on matters specified in the *National Statement*, and other information to the NHMRC on request.
- viii. Submit a written report, annually, to the University Research Committee and Academic Board on:
 - numbers and types of projects assessed and approved or rejected;
 - actions that have supported the educational and training needs of HREC members and people involved in human research;
 - administrative and other difficulties experienced; and

- any matters that may affect the University's ability to maintain compliance with the *National Statement*.

3.2 Membership

The Committee consists of a core membership in accordance with specifications in the *National Statement*: chair; layman and laywoman not affiliated with the institution and not engaged in medical, scientific, legal or academic work; person with experience in the professional care, counselling or treatment of people; person who performs a pastoral care role in the community; lawyer; and members of the academic staff with knowledge of and current experience in the areas of research regularly reviewed by the Committee. Several members are external to the University. All members are appointed by the Vice Chancellor.

3.3 Non-HREC 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.

Section 4 UC Guidelines for responsible practice in research

The University's [Responsible Conduct of Research Policy](#) includes a Preamble, Code of Conduct for responsible practice of research, and detailed procedures for dealing with allegations of misconduct in research.

University researchers have a responsibility to ensure that all research complies with the Guidelines. Applicants seeking HREC approval for their projects should pay particular attention to the section on ethical considerations, including the following specific issues:

- Management of research data;
- Publication
- Authorship;
- The role of research supervisors; and
- Disclosure of potential conflict of interest.

Applicants are required to declare their compliance with University policy on the retention and storage of data in the ethics application form. It should be noted that the policy applies to ALL data associated with research projects including, for example, separately-stored codes linking de-identified data with individuals.

Section 5 HREC Principles and Guidelines for Research with Human Participants

5.1 General principles

This section provides guidance for those intending to work with human participants in a way which may be considered research in terms of the *NHMRC National Statement*

According to the *National Statement*, research is defined as the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies and understandings. This could include synthesis and analysis of previous research to the extent that it leads to new and creative outcomes.

This definition of research is consistent with a broad notion of research and experimental development (R&D) as comprising of creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of humanity, culture and society, and the use of this stock of knowledge to devise new applications.

Certain teaching-related research activities that involve the collection of personal records or have the possibility of an adverse effect on participants are included in this definition. The principles and guidelines set out below are designed to assist University staff and students to determine which activities require approval by the Human Research Ethics Committee and which do not.

It is University policy, regarding research involving humans, to follow appropriate codes of professional conduct and, in particular, to meet the requirements of the NHMRC in its *National Statement*.

Within the framework of guidelines in this section, the HREC should receive an Application Form for each research project directly involving human participants, as detailed in Section 6. **Projects cannot commence before HREC approval is granted.**

5.2 Responsibility for deciding when ethics approval is required

The following pages include criteria on which activities are reviewable by the HREC and which are not. Final responsibility for deciding when application to the HREC is required rests with the following individuals:

- For research conducted as part of the requirements for undergraduate degrees or higher degrees by coursework, it is the responsibility of the research supervisor or unit convenor to determine if a project requires approval by the HREC.
- For supervised projects conducted for research degrees, this responsibility is held by the principal researcher in consultation with the supervisor.
- In all other (i.e. unsupervised) research, the principal researcher is responsible for deciding when approval is required.

5.3 Activities classed as research involving humans

Activities which are classed as research involving humans, and which therefore require application to the HREC, include:

(a) Physiological or psycho-social experiments (other than for professional treatment of a subject)

- Procedures which are interventional or invasive.
- Those which involve taking tissue (including blood) samples or making invasive physiological or psycho-social measurements.
- Those involving administration of any substances to participants.
- Those involving responses to an abnormal stressful stimulus or activity (stressful beyond the normal experience of the participant, including personal embarrassment).
- Those involving recording personal, physiological or psycho-social data recorded together with the participants identity.

(b) Qualitative data collection

- Interviews in which the researcher talks to one or more participants, where the categories of response are focused but not necessarily pre-determined. Interviews can take many forms, including structured, semi-structured, unstructured and focus groups.
- Survey data collection in which the participant can be identified with the data collected, or conclusions drawn from it, regardless of whether the information collected could be regarded as personal or sensitive.
- Survey data collection when the information collected could be regarded as personal or sensitive, whether anonymous or not.
- Observations, case studies, on-line research and archival research as well as analysing media items such as video and/or audio recordings and magazines.
- Action research which involves testing of ideas in practice as a means of improving social, economic or environmental conditions and increasing knowledge.

Where applicable, such data collection must comply with the relevant principles of the Commonwealth Privacy Act (see section 2.2 of this manual).

For surveys not containing questions which may cause offence, where the participant is anonymous and a non-dependant adult, and there is no pressure applied to participate in the questioning, no proposal needs be made to the HREC for the survey. However, the University will require the survey to be conducted according to accepted social and professional ethics.

Ethics approval must be sought if participation in the project involves, for participants, risk of physical or psychological stress, inconvenience or discomfort beyond the normal experience of everyday life, in either the short or long term.

In all research in the above categories, informed consent of the participant (and/or if appropriate the participant's legal guardian, as set out in the *National Statement*) is necessary, as is the right of the participant to withdraw from the research at any time without penalty. Requirements for obtaining informed consent are outlined in [section 6.4](#).

5.4 Activities NOT included in the definition of research involving humans

Activities which are not classed as research involving humans, and which therefore do not require application to the Committee, include:

(a) Class teaching exercises of the following type:

- Teaching activities which conform to the code of ethics and practice of a recognised professional association.

Teaching activities conducted in University of Canberra classes of a type other than as set out in [section 5.3](#), for which there is no foreseeable risk other than inconvenience.

- Laboratory-based teaching involving experiential learning principles which follow standard educational practice of recognised educational institutions.

Note: Class experiments/teaching exercises where there is no foreseeable risk, and from which no personal records will be stored, need not be the subject of a proposal to the HREC. If such an exercise is a requirement for a unit of study, and this is stated to be so in the unit description which is made available to the student at the start of the semester, no proposal is necessary.

(b) Professional practice/consultation

This type of activity is covered by the codes of ethics and practice of the relevant professional association and need not be the subject of a proposal to the HREC unless the activity is also part of an experiment using human participant(s). Where a student is involved in a professional practice program involving human participants (eg external work experience) the supervisor, who is a staff member of the University and subject to the professional codes, must take full responsibility for the observance, by the student, of those codes. It follows that the student must be provided with details of the relevant professional codes of ethics and practice and that the supervisor ensure that the student is familiar with their requirements before undertaking the program. The student must also be informed of legal requirements (e.g. privacy legislation) for which the student and supervisor are personally responsible.

5.5 Research projects involving more than one institution

Projects involving more than one institution may take several forms:

- University of Canberra staff or students may be principal researchers in a project conducted in more than one institution;
- University of Canberra staff or students may be co-researchers in a project initiated by another institution;

In general, HREC approval is required for research projects if any principal researcher or co-researcher is a member of staff (i.e. employee or adjunct) or an HDR student at the University of Canberra, unless a properly constituted Human Research Ethics Committee at another institution has already approved the project, in which case cross-institutional approval can be sought with relevant documentation.

Section 6 Making an Application for Approval

6.1 Responsibilities of staff

In its deliberations the HREC is charged with assessing the qualifications and experience of the researcher(s) and (if applicable) the supervisor of the proposed research. Both must be suitably qualified and experienced to carry out the research project.

The University has a duty of care in its conduct of research. This is exercised by staff in both an immediate and ongoing sense. Where difficulties arise records must be kept of problems and alleviating or rectifying action taken by the researcher, supervisor or other appropriate member of staff.

Researchers and supervisors should be familiar with the University's [Research Conduct and Governance Policy](#). Other policies and documents relating to ethics may be consulted through the university's web site.

6.1.1 Unit coordinators / staff involved in teaching-related research activities

Unit conveners should ensure that ethics applications are submitted for all work within the unit that requires approval by the HREC, e.g. where students are subjects in laboratory experiments.

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 HREC may grant approval for that length of time on condition that the member of staff:

- provides a full application 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 Committee), together with a copy of the Informed Consent statement for that year; and
- returns a project review form on request each year.

6.1.2 Student research

If the principal researcher is a student, the supervisor (the unit co-coordinator) must be a member of staff of the University.

Responsibilities of research supervisors are set out in the University's [Higher Degree by Research Supervision Policy](#).

Unit co-coordinators should be conversant with the National Statement, the requirements of the Commonwealth Privacy Act 1988 and this Manual. They should guide students in the design of projects and ensure that proposals are complete before being submitted to the Committee for consideration. Unit co-coordinators are also required to assist principal researchers with making provision for the storage of data at the University.

In signing the Declaration by the unit co-coordinator on the HREC application form, the unit convenor attests that:

- he/she is qualified and authorised to supervise procedures described in the application;
 - the researchers and assistants involved in the project have been fully briefed on procedures and relevant ethical considerations;
 - she/he is aware of the responsibilities set out in the relevant legislation and guidelines; and
- he/she undertakes to ensure that the research is conducted in accordance with Committee requirements, including all conditions of approval, and that project review reports are submitted to the Committee as required. (Note: If a principal researcher who is a student cannot be contacted or fails to return a project review form, the unit co-coordinator is responsible for completing and returning the form on the student's behalf.)

Contact details for the project supervisor must be provided to participants and potential participants in student research. The following guidelines apply:

- For research conducted as part of the requirements for undergraduate degrees or higher degrees by coursework, the supervisor or unit co-coordinator is the appropriate person to provide additional information or answer inquiries about the project, and to act as the first point of reference in case of concerns and complaints.
- For research conducted for higher degrees by research, the student should be named as the first point of contact, with the supervisor listed as a secondary source of information or advice if the student is unavailable.

6.2 Presentation of research proposals by applicants

Applications for approval to conduct research involving human participants must be submitted through the university's online Ethics Application Form. The form can be found here: [Ethics Form](#).

Applicants must provide the Committee with copies of all documentation associated with the research proposal, including information sheets, consent forms, questionnaires, advertisements and letters of invitation.

If any part of a proposed project is to be carried out at another institution or research site, evidence of approval from the other institution(s) must be provided to the Committee before the project commences.

If restricted information (i.e. existing records which identify individuals, but which are not normally available to the public) is to be used in the project, evidence of agreement from the individuals or organisations which control access to the restricted information must be supplied to the Committee. If a researcher using restricted information will have access to identifying information about individuals, it is expected that the consent of those individuals will be obtained.

6.3 Guidelines for composing an informed consent statement

Informed consent requires that the participant understand the research experiment or procedure having been fully briefed on its purpose and conduct, and that she/he gives consent to participate in that state of knowledge. The consent of the participant is to be recorded, and notes kept of the date(s) of briefing and of the person briefing.

Unless participation is to be anonymous (e.g. in an anonymous survey where return of the questionnaire may be taken as evidence of consent), the consent form is to be signed and dated by the participant (or by the parent or guardian of a child who is the participant). A copy should be provided to each participant (including the parent/guardian where applicable).

Researchers must respect the developing capacity of children and young people to be involved in decisions about participation in research. (Refer to Chapter 4.2 Children and Young People in the *National Statement*). The child or young person's particular level of maturity has implications for whether his or her consent is necessary and/or sufficient to authorise participation. Specific consent to a child's or young person's participation in each research project should be obtained from:

- The child or young person whenever he or she has the capacity to make this decision and
 - either one parent, except when, in the opinion of the review body, the risks involved in a child's participation require the consent of both parents; or where applicable
 - the guardian or other primary care giver, or any organisation or person required by law.

The Committee believes that it is inappropriate for the consent form to be signed by the researcher.

Provision for the researcher's signature could carry the suggestion of a contract, which is inconsistent with the principle that participants may withdraw from the project at any stage without penalty.

The consent form should use wording that is understandable and appropriate to the participant population. Jargon and technical terminology must be avoided or explained in plain English. The consent form must not include any statement which could be construed as an inducement or pressure to participate.

The NHMRC requires information on procedures for raising concerns or complaints about the conduct of research projects, and the appropriate person to receive complaints, to be included when information on the research is first provided to participants. The Committee has developed a pro forma for researchers to use for this purpose (see [section 9.2](#)).

Information sheets and consent forms should be printed on University letterhead in accordance with the UC template guide.

To prevent unnecessary delays in obtaining approval, applicants to the Committee are strongly urged to cross-check their informed consent documentation, when drafted, against the guidelines in this section and the following list of required details.

Forms used to seek consent should include:

- Title of project, a description and purpose of the research or experiment and the procedures to be used.
- Name of researcher, telephone and/or fax number, email if appropriate and address at the University of Canberra. If the researcher is a student, state the course of study and School. (The researcher's home/business contact details should not be used.)
- Name, School and contact details for the supervisor in the case of student research projects.
- A statement that the research project has been considered and approved by the University of Canberra HREC.
- A description of the benefits to be expected from the research.
A statement of what the participants will be expected to do.
- Duration of participation for participants.
- Details of any risks, discomforts, hazards and possible side effects. (Inform participants of any specific medical conditions which should preclude their participation in the research.)
- Where more than minimal discomfort is involved, a description of emergency procedures, medical treatment or counselling services that will be made available.
- A description of the safeguards to be used to protect the participant.
- A statement of the terms of compensation (eg payment) for participation, if any.
- A statement that the identity of participants will not be disclosed and that the data collected will be securely stored and not disclosed.
- A statement of where the data associated with the project will be stored (ie at the University on completion of the project. If records will be stored off-campus at any stage during the project, this should be stated and security arrangements outlined), the required period of storage, details of access and discard.
- A statement on participants' access to results and/or reports or appropriate feedback.
- A statement that participation is voluntary and that participants may withdraw at any stage without penalty or avoid answering questions they do not wish to answer.
- An offer to answer any enquiries concerning the research. (NB: Follow guidelines in [section 6.1.2](#) on who is the appropriate person to answer inquiries about the project and act as the first point of reference in case of concerns and complaints.)
- If appropriate, include a form of words above the space for a signature such as I have read and understood the information provided. I am not aware of any medical condition that would prevent my participation, and I agree to participate in this research.

Section 7 Committee Evaluation of Applications

Full details regarding meeting procedures and decision-making procedures are available in the [Committee Working Procedures](#).

7.1 Committee decision making

All **high risk applications** submitted to the Research Ethics & Integrity team before or on the due date are considered by the Committee at the meeting immediately following that date provided they are complete. New applications are considered only at scheduled meetings of the Committee. As required by the National Statement, all Committee members are fully informed by receipt of all relevant papers and have an opportunity to contribute their views in the decision-making process on each application.

Two assessors are selected to assess each application in advance of the meeting. However, to ensure that the broadest view is brought to bear on each application, the whole Committee has the opportunity to comment on any application being considered by the HREC at the meeting.

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 as needed.

After considering each application, the Committee reaches agreement on specific points to be communicated to the applicant and selects one from the following range of decisions:

(a) Approved with no changes

The project may proceed as submitted.

(b) Approved subject to minor or major changes

The project may proceed subject to specified minor or major revisions. The applicant must provide amended sections of the application and any further documentation to the Research Ethics & Integrity team, who will check to ensure that requested changes have been made.

(c) Not approved Chair to reconsider

The applicant must respond to specified matters raised by the Committee and provide amended and/or further documentation to the Research Ethics & Integrity team for reassessment of the proposal by the Chair. The Chair will review the revised application as soon as possible after receipt and make a decision according to the range of choices listed in this section.

(d) Not approved Resubmit

The applicant must address major issues raised and resubmit the application to the Committee at a subsequent meeting.

(e) Not approved

The Committee may reject an application which fails to meet Committee requirements, eg a research project for which approval has been sought retrospectively. In rare circumstances, the Committee may assess a proposal as completely unacceptable.

(f) Approval not required

The Committee may decide that a research proposal does not require approval by the Committee.

Low risk applications will be assessed by the Low Risk Panel. Decisions made by the Low Risk Panel will be ratified by the HREC at the next available meeting.

7.2 Notification of decisions

Applicants are notified of the Committee's evaluation after the meeting date. The Committee provides reasons for its decision and comments to applicants through the Online Application Form.

In all cases when changes to applications are required, approval is not complete (and **projects may not commence**) until amendments have been received and confirmed as satisfactory by the Research Ethics & Integrity team.

When approval is granted for a research project, applicants will receive an automated approval letter setting out the conditions of approval.

The evaluation provided to applicants should explain fully why the Committee made its assessment and what changes to applications are required. However, further information or clarification of Committee decisions may be sought through the Research Ethics & Integrity team if required. Concerns from applicants or supervisors about Committee consideration of research applications should be raised in the first instance with the Manager, Research Ethics & Integrity.

Section 8 Conditions of Approval

Approval of research projects is subject to conditions determined by University policy and the National Statement.

8.1 Dates and periods of approval

- a. **Starting date:** The Committee cannot grant retrospective approval. If, as a result of changes required by the Committee, the starting date nominated by the researcher on the application form precedes the date of final approval, the approval period is deemed to begin on the date at which the project was approved.
- b. **Maximum period:** The maximum period of approval to be granted by the Committee is three years. Researchers engaged in projects lasting longer than one year must submit annual reports (see the following section). Special conditions apply to staff projects repeated annually as teaching exercises (refer to [subsection 6.1.1](#)).
- c. **Alteration or extension of period of approval:** If a project will not be complete by the approval expiry date, or the period of approval needs to be amended for any reason, the researcher must apply in writing for alteration or extension of approval. Application should be made before current approval expires; should specify a new completion date; should explain why the amendment is necessary; and should be endorsed by the project supervisor (if applicable).
- d. **Discontinuation of research:** The researcher (in conjunction with the supervisor, if applicable) should inform the Committee, giving reasons, if the research is not conducted or is discontinued before the expected date of completion.

8.2 Other conditions of approval

Monitoring

A researcher, in conjunction with the supervisor where applicable, must assist the Committee to monitor the conduct of approved research by completing and promptly returning project review forms, which will be sent to researchers at the end of a project, and, in the case of extended research, at least annually during the approval period.

Immediate reports of changes in protocol or unexpected events

A researcher must immediately report to the Committee anything which might warrant review of ethical approval of his/her 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.

Retention and storage of data

University policy states that all research data must be stored securely, on University premises, for a minimum of five years (refer to [section 4](#)). The researcher and supervisor (if applicable) must ensure that all records are transferred to the University when the project is complete.

Contact details and notification of changes

Researchers are asked to advise the Committee of changes of address, email etc during and/or immediately after the approval period. All email contacts should use UC email addresses if possible.

Section 9 Monitoring the Conduct of Research

Under the National Statement, the Committee is responsible for monitoring research for which it has given approval. The principal mechanism for monitoring is project review reports.

9.1 Project review reports

The National Statement states that as a minimum a Human Research Ethics Committee must require at regular periods, at least annually, reports from principal researchers on matters including:

- 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.

It is a condition of approval that researchers assist the Committee to monitor the conduct of approved research by completing and promptly returning project review reports. Report forms are sent to principal researchers at the end of the project and, in the case of extended research, at least annually during the approval period.

Where the researcher 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 may be asked to complete and return the form on the researcher's behalf.

9.2 Complaints about the conduct of research

The National Statement requires that Human Research Ethics Committees establish mechanisms for handling complaints about the conduct of research, and that information on these mechanisms is provided to all participants in approved research projects.

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.

The following guidelines apply to complaints about projects approved by the HREC (see also Responsibilities of research supervisors in [subsection 6.1.2](#)):

- Concerns and inquiries about student research projects conducted as part of the requirements for undergraduate degrees or higher degrees by coursework 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 higher degrees by research, should be raised in the first instance with the principal researcher. The name and contact details of the research supervisor are provided to research participants as 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 Manager, Research Ethics & Integrity. In accordance with the National Statement, contact details for the Manager, Research Ethics & Integrity as the recipient of complaints will be provided to all participants in research involving human participants.

9.3 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.