

Name of Policy	Australian Catholic University Human Research Ethics Committee– Terms of Reference.
Description of Policy	The ACU Human Research Ethics Committee defines the purpose of the Committee for Human Research.
Policy applies to	<input checked="" type="checkbox"/> University-wide <input type="checkbox"/> Specific (<i>outline location, campus, organisational unit, etc</i>)
	<input type="checkbox"/> Staff only <input type="checkbox"/> Students only <input checked="" type="checkbox"/> Staff and students
Policy status	<input type="checkbox"/> New policy <input checked="" type="checkbox"/> Revision of existing policy

Approval authority	Deputy Vice-Chancellor (Research and Enterprise)
Governing authority	University Committee (Research)
Responsible officer	Director, Research Services

Refer to the Delegations of Authority Policy and Register and/or relevant Committees Terms of Reference for further details.

Approval date	19/04/2022
Effective date	18/07/2022
Approval date of last revision	13/05/2015
Effective date of last revision	13/05/2015
Date of policy review*	18/07/2025

**unless otherwise indicated, this policy will still apply beyond the review date*

Related legislation, policies, procedures, guidelines and local protocols	<ul style="list-style-type: none"> • National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) • Australian Code for the Responsible Conduct of Research (2018) • AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020) • Ethical Guidelines for research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018) • Australian Privacy Principles <ul style="list-style-type: none"> ○ NHMRC – Privacy Act 1988 Guidelines – Section 95 ○ NHMRC – Privacy Act 1988 Guidelines – Section 95A • ACU Research Code of Conduct • ACU Research Code of Conduct (and any associated internal policies and procedures)
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1. Purpose

The ACU Human Research Ethics Committee (HREC) is responsible for ensuring that research conducted by ACU staff or students and involving humans as subjects or participants is managed in accordance with the National Statement on Ethical Conduct in Human Research 2007 (the “National Statement”), the Australian Code for the Responsible Conduct of Research (2018) and any associated legislation and guidelines, as well as ACU policies & procedures. In collaboration with the University’s research community, the HREC aims to:

- protect the mental and physical welfare, rights, dignity and safety of human research participants, their data or human tissue;
- protect and promote the reputation of ACU as a place of ethical research by reviewing research, and;
- provide guidance and support to ACU researchers on ethical conduct in human research.
- The HREC will achieve this by:
- reviewing human research ethics applications submitted by staff and students, to assess ethical acceptability and adherence to relevant standards and guidelines;
- reviewing and registering human research ethics applications involving ACU staff or students, and which have been granted ethics approval by another, accredited HREC;
- undertaking expedited review of negligible or low risk human research projects;
- maintaining a register of ethics approval and communicating information on request to appropriate national bodies;
- developing and publishing human research ethics policies and guidelines for ACU researchers and students;
- promoting an understanding of and appreciation for the importance of ethical research conduct by staff and students of the University;
- monitoring the conduct of approved research through internal audits, as well as the receipt of progress, annual and completion reports;
- managing adverse events and undertaking initial investigation of complaints relating to ethics applications, and;
- providing advice to the University, through the Deputy Vice-Chancellor (Research and Enterprise), on ethical issues relating to research.

2. Membership

Membership should reflect a balance of experience, views, expertise and gender, as well as representation from the different University campuses.

Members will be appointed in the following categories:

- a chairperson, with suitable experience, whose other responsibilities will not impair the HREC’s 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 ACU 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, who where possible is not engaged to advise ACU, and;
- at least two people with current research experience that is relevant to research proposals being 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.

Date of Establishment: 1995
Meeting Frequency: 11 times per year
Responsible Officer: Deputy Vice-Chancellor (Research and Enterprise)
Executive Officer: Senior Research Ethics Officer
Revised: April 2022
Review date: July 2025
Approved by University Research Committee: April 2022

3. HREC Operating Procedures

The HREC will be guided by the following values, as outlined in the National Statement:

- Respect
- Justice
- Beneficence
- Research merit and integrity

The HREC will promote these values by ensuring that:

- any decisions made are in accordance with the principles and values of the National Statement;
- research is conducted to a high ethical standard, in accordance with recognised internal and external legislation, guidelines, policies and procedures;
- the rights and interests of research participants take precedence over the expected benefits to human knowledge, the community or to the researcher;
- every reasonable attempt is made to balance potential risk and benefit arising from research;
- local culture, practice and social attitudes are taken into consideration when making ethical decisions;
- communication with researchers is open and respectful, and;
- no members of the HREC adjudicate on proposals in which they may be personally involved.

3.1. VALUES

The Vice-Chancellor (or delegate who is either a decision-making Committee or a Senior Executive Group member) must be listed here. Please note that in web editing (HTML) version, the field will automatically default to the Vice-Chancellor.

3.2. ACCOUNTABILITY

While consensus decisions are the ideal, ultimate responsibility for the approval of human research rests with the Chair of the HREC.

Through the Chair, the HREC reports to the Deputy Vice-Chancellor (Research and Enterprise).

The Deputy Vice-Chancellor (Research and Enterprise) shall:

- on request, be provided with the minutes of each meeting, and other meeting papers, and;
- as necessary, be briefed by the Chair on any research ethics matters of interest or importance.

3.3. ADVERSE EVENTS & COMPLAINTS

Adverse events and complaints relating to approved ethics applications may initially be managed and investigated by the HREC, HREC Chair and the Manager, Research Ethics & Integrity, in line with University policies relating to the responsible conduct of research.

Complaints about the HREC itself, that cannot be resolved by the Chair or Manager, Research Ethics & Integrity, will be referred to the Deputy Vice-Chancellor (Research and Enterprise).

For information on other types of complaints, including complaints relating to research conduct, or general complaints, see the:

- ACU Research Code of Conduct;
- ACU Staff Complaint Management Policy, and;
- ACU Student Complaint Management Policy

3.4. MEMBERSHIP

Appointment of HREC members

In appointing members to the HREC, the following conditions/obligations apply:

- the Chair of HREC will be appointed by the Deputy Vice-Chancellor (Research and Enterprise);
- the Deputy-Chair/s of HREC, the Convenor of the IREAP and ordinary HREC members will be appointed by the Chair of HREC, in consultation with the Deputy Vice-Chancellor (Research and Enterprise) as necessary;
- members of the HREC will hold membership until the 31st of December closest to three years from the date of their appointment;
- members will be appointed in their own right and not as representatives of any group, organisation or opinion;
- members may serve a maximum of two consecutive terms unless otherwise approved by the Chair;
- members may be appointed jointly (i.e., in a role-sharing capacity). It is the responsibility of such members to ensure that one or the other is able to attend each meeting of the HREC;
- prospective members of the HREC will be sought through open and transparent means, including nomination, advertisement and direct approach;
- any interested person may indicate their willingness to serve on the HREC by submitting an Expression of Interest to the Ethics Secretariat;
- all new members are to receive an appropriate induction;
- throughout their term of service, members are to be provided with ongoing education, training and support, with a view to ensuring that they have the skills, knowledge and resources required to fulfil their roles, and;
- the Chair of HREC may terminate the appointment of any other member of the HREC, if they believe doing so is necessary for the proper functioning of the committee.

Responsibilities of HREC Chair

The Chair of the HREC is responsible for:

- upholding and promoting the responsible conduct of research, and providing leadership and guidance to the HREC, researchers and the broader university community with respect to research ethics;
- on behalf of the HREC, granting approval for the conduct of human research;
- Ensuring the HREC functions in accordance with the National Statement, the Australian Code for the Responsible Conduct of Research (2018), the HREC terms of reference, and any associated internal and external legislation, guidelines, policies and procedures;
- chairing meetings in a manner which ensures that the views of all members are received and considered, and that where possible, HREC decisions are consensus-based;

- appointing other members of the HREC, as outlined above;
- making decisions about the most appropriate ethical review pathway for ethics applications, amendments, reports, etc;
- conducting expedited reviews of low and negligible risk ethics applications, and;
- promoting good communication between the HREC, researchers, and the institution.

Responsibilities of HREC Members

Members of the HREC are expected to:

- become familiar and act in accordance with the National Statement, the Australian Code for the Responsible Conduct of Research (2018), the HREC terms of reference, and any associated internal and external legislation, guidelines, policies and procedures;
- review applications and submit their comments on those applications prior to the meeting, for consideration during the meeting;
- attend meetings by teleconference/videoconference or in person whenever possible, or provide an apology prior to the meeting;
- contribute to meeting discussion, and engage with other members in a respectful and inclusive manner;
- consider the ethical implications of proposed research projects on human participants and determine whether these are acceptable;
- monitor research projects until completion so as to ensure ongoing compliance with approved ethical standards, and;
- participate in relevant induction, education and training.

Liability Coverage

The University will provide indemnity for members of the HREC, for any liabilities that arise as a result of the member exercising their duties in good faith.

4. Meeting Conduct

Confidentiality

Members and those in attendance such as observers are asked to respect the confidentiality of meetings.

Decision Making

While consensus-based decisions are preferable, there is no requirement for unanimous decisions and all committee members should have the opportunity to express their opinion.¹ Most importantly, however they are arrived at, decisions must accord with the principles and requirements of the National Statement.

Meeting Frequency

Meetings will normally be held once a month (except January).

4.1. REPORTING

The Ethics Secretariat, in conjunction with the Chair of the HREC, is responsible for the preparation and dissemination of internal and external reports.

Reporting (external)

The HREC will provide annual reports to the NHMRC, as well as any other external report, as required.

¹ In accordance with NS 5.2.33.

Reporting (internal)

The HREC will provide annual report, as well as any other reports on HREC activity, to Deputy Vice-Chancellor (Research and Enterprise)

4.2. REVIEW OF APPLICATIONS

The Ethics Secretariat will “triage” applications to determine the level of review appropriate for the risk and complexity of the research. The Ethics Secretariat will also allocate applications to a particular reviewer, as required.

Expedited Review

Research involving low or negligible risk, including registrations of external applications and modifications, may be reviewed out-of-session by the Chair, Deputy Chair, Acting Chair or other nominee, and ratified at the next full meeting of HREC.

Full HREC Review

All research involving humans that is deemed greater than low risk will be reviewed by the full HREC. Regardless of the risk, HREC review is required when research involves:

- a request for a waiver of consent;
- participants with a cognitive impairment, an intellectual disability, mental illness, or who are highly dependent on medical care, and may be unable to give consent on their own behalf;
- participants who may be involved in illegal activity;
- Aboriginal and Torres Strait Islander peoples, and;
- minors.

Retrospective Review

The HREC cannot provide retrospective approval.

Withdrawal of ethics approval

The Chair has the right to suspend or withdraw ethics approval on behalf of the HREC.

Ethics approval may be withdrawn or suspended in any of the following circumstances:

if the project is not being conducted according to the approved protocol, or if a researcher is failing or has failed to comply with any conditions imposed by the HREC;

- if serious misconduct by a researcher is suspected or proven;
- if a researcher fails to inform the HREC of any adverse events, or of new safety information from other published or unpublished studies that may affect the acceptability of the research;
- if the wellbeing of any participant or participants is compromised;
- if a clinical hold has been placed on the study by the Therapeutic Goods Administration, or another regulatory body, and;
- if a sponsor or researcher remains unresponsive to the HREC’s request for information.

4.3. ADMINISTRATION

Meeting Papers

Agendas are circulated to the HREC at least one week prior to each meeting.

Minutes

The outcomes of each meeting are communicated to researchers in a timely manner, i.e., where possible, within two weeks of the meeting date.

Communication

The Ethics Secretariat is responsible for facilitating open, timely and constructive communication between the HREC and researchers. This includes being available to assist researchers in the interpretation and resolution of HREC deliberations and expedited review comments.

4.4. RELATED LEGISLATION, POLICIES AND GUIDELINES

- [National Statement on Ethical Conduct in Human Research 2007 \(Updated 2018\)](#)
- [Australian Code for the Responsible Conduct of Research \(2018\)](#)
- [AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research \(2020\)](#)
- [Ethical Guidelines for research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders \(2018\)](#)
- Australian Privacy Principles
 - [NHMRC – Privacy Act 1988 Guidelines – Section 95](#)
 - [NHMRC – Privacy Act 1988 Guidelines – Section 95A](#)
- [ACU Research Code of Conduct](#)
- Any associated internal policies and procedures

4.5. REVIEW

The HREC Terms of Reference will be reviewed every 3 years in accordance with ACU policy.