



The University of Queensland  
Human Research Ethics Committee (HREC)  
Terms of Reference  
April 2024



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## 1. Introduction

Human Research is that conducted with or about people, their data or tissue. To be ethically acceptable, human research must comply with the National Statement on Ethical Conduct in Human Research (2023) [National Statement] and demonstrate the values of research merit and integrity, justice, beneficence and respect. To make a judgement that a human research proposal meets the requirements of the National Statement, and is ethically acceptable, the University has established two Human Research Ethics Committees (HRECs).

This document provides the Terms of Reference for the University's HRECs, as per section 5.1.29 of the National Statement.

## 2. Responsibilities

The objectives of the University HRECs are to:

- 2.1. Protect the mental and physical welfare, rights, dignity and safety of participants of research and minimise the risk of harm arising from research studies involving humans.
- 2.2. Promote ethical principles in human research by education of the academic community.
- 2.3. Review research in accordance with the National Statement.
- 2.4. Facilitate ethical human research through efficient and effective review of higher risk research as per UQ's [Human Research Ethics Procedure](#), noting that HRECs may also be used to review lower risk research applications, ratifications and exemption applications on referral by reviewers or the Research Ethics and Integrity office.

The HREC functions on behalf of UQ to:

- 2.5. Provide independent oversight of human research projects in respect of their ethical acceptability, where the research takes place:
  - 2.5.1. At UQ, carried out using equipment, facilities or premises owned by the University and/or the research is undertaken by any person who is a student, staff member or title holder of the University. Title holders refer to: visiting academics, academic title holders, industry fellow, emeritus professors, adjunct honorary title holders, and conjoint appointments.
  - 2.5.2. On limited occasions at locations external to UQ, from researchers who have no affiliation with UQ, on agreement with the Director, Research Ethics and Integrity. External reviews may be charged fee for services as agreed.
- 2.6. Provide competent, timely ethics review and monitoring of human research projects for as long as they are active.
- 2.7. Ensure compliance of human research projects with the principles of the National Statement and other relevant Acts and legislative requirements for that type of research, and grant, withhold, temporarily suspend, or withdraw ethics approval.



- 2.8. Protect the privacy and confidentiality of research participants by ensuring that researchers have considered the appropriate management of data and primary materials in accordance with UQ policy and relevant legislation.
- 2.9. Provide advice to the Deputy Vice-Chancellor (Research and Innovation) or delegate on strategies to promote awareness and understanding of the ethical conduct of human research within UQ and the broader community.

### 3. Accountability

- 3.1 The HREC is accountable to the Deputy Vice-Chancellor (Research and Innovation) or their delegate.
- 3.2 The HREC operates under the guidance of, and is administratively supported by, Research Ethics and Integrity.
- 3.3 The HREC brings to the attention of the Deputy Vice-Chancellor (Research and Innovation) or delegate issues of significant concern.
- 3.4 The HREC reports annually to National Health and Medical Research Council (NHMRC) using that bodies reporting template.
- 3.5 The HREC reports annually to the Deputy Vice-Chancellor (Research and Innovation). The report includes:
  - a summary of membership and membership changes;
  - number of research projects reviewed, approved and rejected;
  - number of annual and final reports received;
  - a summary of any suspension or withdrawal of approvals;
  - a summary of any appeals and complaints received;
  - monitoring procedures for research in progress and issues identified by the HREC in undertaking its monitoring role;
  - general issues including advice on strategies to promote awareness of the ethical conduct of human research; and
  - any resources required to assist the HREC in fulfilling their role.

The annual report will be prepared by Research Ethics and Integrity for consideration and approval by the HREC Chairpersons.

### 4. Membership

HREC members are appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion.

- 4.1 Members are required to:
  - 4.1.1 Become familiar with the National Statement and consult other guidelines relevant to the review of specific research proposals.



- 4.1.2 Prepare for and attend scheduled meetings of the review body or, if unavailable, provide opinions on the ethical acceptability of research proposals before meetings, subject to institutional policies on absences.
- 4.1.3 Participate in subcommittee meetings, review or monitoring of approved research, or out of session reviews.
- 4.1.4 Attend continuing education or training programs in research ethics.
- 4.1.5 Disclose any associations that may represent a conflict of interest.
- 4.2 The composition of the HREC is in accordance with the National Statement. Minimum membership comprises eight members:
  - a Chairperson with suitable experience, including previous membership of an HREC, whose other responsibilities will not impair the HREC capacity to carry out its obligations under the National Statement;
  - two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution;
  - a person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional;
  - a person who performs a pastoral care role in the community, including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a or a minister of religion or other religious leader;
  - a qualified lawyer, who may or may not be currently practicing and, where possible, one who is not engaged to advise the institution on research-related or any other related matters; and
  - two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

As far as practicable, membership at each meeting will reflect the diversity, including gender diversity, of the UQ community and at least one third of the members will be external to UQ.

- 4.3 Members additional to the eight members identified in 4.2 may be appointed.
- 4.4 An individual may fill more than one category at separate meetings, providing that the minimum membership categories are represented at each meeting. No individual may represent more than one of the categories at any individual meeting. Members are eligible to attend any of the Universities HRECs.

## 5. Appointments

- 5.1 HREC members are recruited by direct approach, nomination or by advertisement through an open and transparent selection process.
- 5.2 Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of new viewpoints.
- 5.3 Prospective members are asked to provide a copy of their curriculum vitae to the Chairperson and Research Ethics and Integrity. The Chairperson makes a



recommendation on new appointments to the Director Research Ethics and Integrity or delegate.

- 5.4 Prospective members may be invited to observe a meeting of an HREC.
- 5.5 All members of the committee, excluding the Chairperson, will be appointed by the Director Research Ethics and Integrity. The letter of appointment will include the date of appointment, length of tenure, indemnity, remuneration and acceptance of HREC Terms of Reference.
- 5.6 The Director Research Ethics and Integrity will provide guidance on remuneration for external volunteers appointed to an HREC. An honorarium is offered to assist with covering costs associated with review of applications and attendance at meetings. The letter of appointment will detail the honorarium offered.
- 5.7 The Chairperson is appointed by the Deputy Vice-Chancellor (Research and Innovation) or delegate. The letter of appointment includes the date of appointment, length of tenure, indemnity and acceptance of HREC Terms of Reference.
- 5.8 All members sign a conflict-of-interest declaration, which will be maintained on the member's personnel file.
- 5.9 Upon appointment, members are provided with an orientation package, inducted and asked to sign a statement undertaking:
  - that all matters of which the member becomes aware during the course of their work on the HREC will be kept confidential;
  - that any conflicts of interest within meetings, which exist or may arise during the members tenure on the HREC, will be declared;
  - that the member has not been subject to any criminal conviction or disciplinary action, which may prejudice their standing as a HREC member.
- 5.10 Members are appointed for a maximum initial period of 3 years. Subsequent reappointment will occur subject to committee requirements.
- 5.11 Membership lapses if a member fails to:
  - attend three consecutive meetings without reasonable justification or in exceptional circumstances;
  - attend at least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances;
  - complete training or professional development related to their role as a HREC member as required by the HREC Chairperson or University.
- 5.12 The appointment of any member of the HREC may be terminated if the Chairperson is of the opinion that:
  - it is necessary for the proper and effective functioning of the HREC;
  - the person is not a fit and proper person to serve on an HREC;
  - the person has failed to carry out their duties as an HREC member.
- 5.13 The Director Research Ethics and Integrity or delegate notifies the member of a lapse or termination of membership in writing.



- 5.14 Members seeking to resign or take a leave of absence for an extended period from the HREC are asked to provide at least four weeks written notice to the Chairperson and HREC coordinator so that steps can be taken to fill the vacancy.
- 5.15 Members are expected to participate in sub-committees if required.
- 5.16 UQ provides indemnity for members of the HREC for liabilities that arise as a result of the member exercising their duties in good faith.
- 5.17 Membership of the HREC, including member name and category of membership, may be made publicly available (with member's consent) on UQ's web site.

## 6. Role of Chairpersons and Deputy Chairpersons

Duties and responsibilities include, but are not limited to:

- 6.1 Upholding the responsibilities of the HREC Chairperson role in accordance with the National Statement and UQ HREC Terms of Reference and Standard Operating Procedures.
- 6.2 Providing leadership and impartial guidance to the HREC in relation to the responsible and ethical conduct of research. This includes ensuring reviews are consistent with the National Statement, Australian Code for the Responsible Conduct of Research, and all relevant Acts, legislation, codes and guidelines applicable to human research.
- 6.3 Fostering appropriate education and training in relation to human research ethics to HREC members, researchers and students.
- 6.4 Preparing for and chairing HREC or sub-committee meetings, including managing disclosure of interest declarations and the business of meetings in accordance with the meeting agendas.
- 6.5 Chairing HREC or sub-committee meetings in a manner that ensures the views of all members are received and considered and that consensus-based decisions are made where possible.
- 6.6 Liaising with the committee's secretary regarding post-meeting procedures, including reviewing draft minutes and committee responses to applicants in a timely manner.
- 6.7 Promoting good communication between the HREC, researchers and the University.
- 6.8 Contributing to the development and/or review of UQ policies, procedures and operational guidelines related to human research ethics and the HREC.
- 6.9 Attending to routine and arising matters between meetings, including reviewing amendments, reports and complaints about the conduct of approved research in a timely manner.
- 6.10 Providing guidance and advice to the UQ research community.
- 6.11 Promoting awareness of human research ethics principles, processes, and procedures.
- 6.12 Assisting with recruitment and training of HREC members.
- 6.13 Representing UQ in human research ethics forums.



- 6.14 Supporting the monitoring of compliance and safety in human research.
- 6.15 The Deputy Chairperson can substitute for the Chairperson in their absence or when required due to workload or a conflict of interest.

## 7. Sub-committees

- 7.1 The HREC may appoint sub-committees to assist the University to meet requirements of the National Statement. Members of the sub-committee need not be members of the HREC.
- 7.2 The minutes and decisions of a HREC sub-committee are noted and endorsed at the next HREC meeting, and any matters of significance (e.g., serious adverse events) will be included on the agenda of the next HREC meeting.

## 8. Executive Committee

- 8.1 The HREC has an Executive Committee comprising, at a minimum, the HREC Chairperson or their delegate and a member from Research Ethics and Integrity.
- 8.2 The purpose of the Executive Committee is to undertake expedited review and approval of business that does not require review by the full HREC. Business that can be delegated to the Executive Committee is determined by the HREC and outlined in the HREC Standard Operating Procedures.
- 8.3 The minutes and decisions of the HREC Executive Committee are noted and endorsed at the next HREC meeting, and any matter of significance (e.g., serious adverse events) will be included on the agenda of the next HREC meeting.

## 9. Operations

### 9.1 Procedures

- 9.1.1 The HREC conducts its business in accordance with this Terms of Reference and any Standard Operating Procedures, noting National Statement guidance in section 5.2 of that document.
- 9.1.2 The HREC Terms of Reference are made publicly available on UQ's web site.

### 9.2 Meetings

- 9.2.1 The HREC aims to meet on a regular basis approximately every four weeks, where there is need. Up to 12 scheduled meetings in each year are held for the purpose of reviewing new applications. Only one committee will usually meet in the months of December and January.
- 9.2.2 Meeting dates and application-closing dates are made available on UQ's web site. The Chairperson, in discussion with Research Ethics and Integrity, can cap applications submitted for review at meetings to ensure the committee has time to adequately consider all ethical issues.
- 9.2.3 Where there is less than full attendance of the minimum membership at a meeting (eight members, and at least one third of members should be from





outside the University), before a decision is reached the Chairperson should be satisfied that the views of those absent who belong to the minimum membership have been received and considered.

9.2.4 Researchers may be invited (or researchers may request) to present for discussion of, but not deliberations about, their proposed research. Participation of researchers in HREC meetings is at the discretion of the HREC Chairperson.

9.2.5 The HREC is free to consult any person considered by the HREC to be qualified to advise and assist in reviewing applications, provided that there is no conflict of interest and an undertaking of confidentiality is given. Such person(s) is (are) not entitled to vote on any matter.

### 9.3 **Declaration of interest**

9.3.1 HREC members must declare associations that may give rise to any actual, potential or perceived conflict of interest at the commencement of a meeting. Should a member identify a conflict of interest at any time during the meeting, this must be declared at that time.

9.3.2 The minutes record declarations of interest and the decision of the HREC on how any conflict of interest is managed.

### 9.4 **Confidentiality**

9.4.1 HREC meetings are held in private. The agenda and minutes of meetings, applications, supporting documentation and correspondences are all treated confidentially.

9.4.2 All human research ethics applications are treated as confidential and will not be shared for purposes other than undertaking or assessing the ethics review, unless agreed to by the applicant or required by an authorised process or officer of the University (e.g., an application may be shared for the purpose of an investigation into the conduct of the research in question).

9.4.3 The HREC may invite observers to attend meetings. Any invited observers should not be involved in deliberations or decision making and are still bound by the same confidentiality and disclosure of interest requirements as HREC members.

### 9.5 **Decision making**

9.5.1 The HREC endeavours to reach a decision concerning the ethical acceptability of an application by unanimous agreement. An HREC can:

- approve the application as being ethically acceptable;
- request modification or further information/clarification;
- seek further advice from external expert reviewer(s); or
- reject the application.

9.5.2 Where a unanimous decision is not reached, the Chairperson will facilitate the expression of opinion from all members, identify points of agreement and of disagreement and judge when a sufficient degree of general agreement has been reached.

9.5.3 Any significant minority view can be noted in the minutes on request.



9.5.4 The HREC may delegate some of its responsibilities to its Chairperson, one or more of its members, a sub-committee, executive committee or administrative officers. Action taken by delegates should be ratified by the HREC.

## 9.6 **Records**

9.6.1 Research Ethics and Integrity will prepare and retain written records of all meetings, including agendas and minutes of all meetings of the HREC, HREC sub-committee and the HREC Executive Committee.

9.6.2 Research Ethics and Integrity will prepare and maintain an official file for each application received, including a copy of the application and any other relevant correspondence between the applicant and the HREC.

9.6.3 Research Ethics and Integrity will also maintain a database of all the applications received and reviewed in accordance with the National Statement.

9.6.4 Records will be held as per University requirements and under the relevant State Retention and Disposal schedule.

## 9.7 **Monitoring research projects**

9.7.1 The HREC monitors approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. This includes review of annual progress reports and final reports, safety reports and reports of protocol violations.

9.7.2 The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived, including:

- discussion of relevant aspects of the project with investigators, at any time;
- audits of compliance with the approved protocol;
- random inspection of research sites, data, or consent documentation;
- interview with research participants or other forms of feedback from them;

and

- request and review reports from independent agencies or persons, such as a Data and Safety Monitoring Board.

9.7.3 The HREC also has the discretion to recommend in the letter of approval that the researcher coordinates onsite monitoring at recommended intervals or randomly throughout the project.

## 10. Appeals and Complaints

### 10.1 Action regarding HREC rejection

Where the HREC has rejected an application, the applicant may lodge an appeal with the Chairperson (via Research Ethics and Integrity) specifying the grounds of the appeal in writing. The Chairperson will provide a response in writing.

An applicant may also submit a new application to the same HREC, taking due account of the committee's feedback.

### 10.2 Appeals on the basis of process

If an applicant considers that the HREC has failed to follow due process, and the matter cannot be resolved through discussion with the HREC, they may lodge a complaint with the Director, Research Ethics and Integrity, in accordance with the UQ [Human Research Ethics Procedure](#).

### 10.3 Complaints about the conduct of HREC members

Complaints about the conduct of an HREC member are managed by the Director Research Ethics and Integrity or delegate who, where appropriate, informs the Chairperson of the complaint. Complaints about the conduct of the HREC Chairperson are managed by the Deputy Vice-Chancellor (Research and Innovation) or delegate.

### 10.4 Complaints about the conduct of an approved research project

Complaints about the conduct of an approved research project are managed by the relevant Chairperson, with assistance from Research Ethics and Integrity. Complaints that represent a potential breach of the Australian Code for the Responsible Conduct of Research are managed in accordance with UQ's complaint handling procedures (see the UQ [Human Research Ethics Procedure](#) for details).

## 11. Review of Terms of Reference and Termination

11.1 These Terms of Reference will be reviewed every three years and may be amended in consultation with the HREC.

11.2 Where the HREC is to be merged, closed or has ceased to function, UQ notifies the NHMRC and determines the appropriate course of action, such as the status of its registration with the NHMRC and the monitoring of previously approved research.

### 11.3 Revision history

Version	Approval date	Effective date	Extent of revision
1.0	June 2016	June 2016	First release for newly formed committees (HREC A and HREC B) after major restructure of UQ's human research ethics review processes.
2.0	29 April 2024	29 April 2024	Significant revisions to reflect changes to National Statement and UQ's operational environment.

End-of-document