University of Western Australia

Human Research Ethics Committee

Terms of Reference

1. Introduction

'Human research' means research involving people, their data, or their biospecimens. 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 a Human Research Ethics Committee (HREC).

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

2. Responsibilities

The UWA HREC is responsible for the following:

a) Review of applications for ethics approval for human research involving UWA staff and students and deemed to be higher risk according to the National Statement on Ethical Conduct in Human Research, 2025 (National Statement).

b) Aspects of monitoring of UWA HREC approved human research projects.

c) Receiving reports of incidents and complaints about the conduct of research, and assist in resolution as required with participants, researchers, or others on the conduct of projects.

d) Provide advice and expertise to the university on matters pertaining to human research ethics.

3. Accountability

a) The UWA HREC is a committee functioning under the authority of the Deputy Vice Chancellor, Research (DVCR).

b) UWA shall indemnify members of the UWA HREC for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith.

c) The UWA HREC may from time to time bring to the attention of the DVCR issues of concern to the UWA HREC.

d) The UWA HREC will provide an annual report to the NHMRC in accordance with the requirements of the NHMRC and the National Statement, including information on membership, the number or proposals reviewed, status of proposals, a description of any complaints received, and their outcome and general issues raised. A copy of this report will be provided to the DVCR.

e) These Terms of Reference shall be altered on the recommendation and approval of the DVCR. The Manager, Research Ethics and Compliance (REC) or HREC Chair shall be responsible for initiating this process. The HREC members will be consulted in the amendment of the Terms of Reference, which are ratified by DVCR.

4. Membership

a) HREC Membership is appointed by the DVCR.

b) Membership of the committee will satisfy the requirements of the National Statement sections 5.1.30 – 5.1.36. The minimum membership is:

   i. A Chairperson (Chair), with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement.

   ii. Two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution.

   iii. A person with knowledge of, and current experience in, the professional care, counselling, or treatment of people, for example, a nurse or allied health professional.

   iv. A person who performs a pastoral care role in a community, including, but not limited to, for example, an Aboriginal and/or Torres Strait Islander elder, chaplain, or minister of religion or other religious leader.

   v. A lawyer, who may or may not be currently practising and, where possible, one who is not engaged to advise the institution on research-related or any other matters.

   vi. Two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

c) Membership should include a person who has knowledge of research with Aboriginal and Torres Strait Islander people and communities or are familiar with relevant cultural knowledge, if such a person has not already been appointed in the membership category listed in b).

d) At least one-third of HREC members will be external of the university.

e) No member may represent more than one of the categories listed at any individual meeting, but they may fill a different category at a separate meeting, as long as all minimum membership categories are represented at each meeting.

f) As far as practicable, membership at each meeting will include diversity, including gender diversity.

g) Membership will include a representative of the UWA Research Ethics and Compliance office who is an *ex officio* observer member of the HREC. The *ex officio* member can take part in discussions but does not take part in decisions.

5. Appointments

5.1 Method of appointment

a) UWA HREC members are recruited by direct approach, nomination or by advertisement.

b) Appointments will allow for continuity, the development of expertise within HREC and the regular input of new viewpoints.

c) Prospective members apply by providing a copy of their curriculum vitae and expression of interest to the HREC Chair and Manager, REC. The Chair makes a recommendation on new appointments to the DVCR.

d) Prospective members may be invited to observe a meeting of an HREC.

e) Once appointed, the letter of appointment will include the date of appointment, length of term, indemnity, remuneration (if applicable) and acceptance of HREC Terms of Reference.

f) UWA HREC members will be provided with documents to assist with carrying out their responsibilities, which includes but is not limited to: National Statement; Australian Code for Responsible Conduct in Research and UWA HREC Terms of Reference.

g) All new members to the UWA HREC will be provided with an induction and information session. This is the responsibility of the REC office.

5.2 Terms of appointment

Upon accepting appointment to a committee, members agree to:

a) Maintain familiarity and serve in accordance with the relevant codes and guidelines, including but not limited to the National Statement.

b) Review meeting papers and lodge application review comments in ROAP prior to committee meetings.

c) Attend meetings approximately once monthly (or as scheduled) for their duration or, in the case of inability to attend, give advance notice of absence to the Research Ethics and Compliance (REC) Office.

d) Attend a minimum of two thirds of their scheduled monthly UWA HREC meetings.

e) Provide advance notice to the REC Office as early as possible if planning to resign from the committee.

f) Attend information sessions and other training seminars provided by the University, as required.

g) Disclose any actual, perceived, and potential conflicts of interest that may affect their unbiased conduct.

h) Protect the confidentiality of the content of applications and the deliberations of the UWA HREC.

6. Role of the HREC Chair

a) The Chair of the UWA HREC (Chair) is appointed by the DVCR.

b) The UWA HREC Chair is responsible for Chairing UWA HREC meetings in a manner that ensures the views of all members are received and considered and that consensus-based decisions are made where possible.

c) The Chair liaises with the SEO and EOs regarding post-meeting procedures, including reviewing draft minutes and committee responses to applicants in a timely manner.

d) The term of appointment of the Chair is three years from the date of the Chair's appointment. The Chair may be reappointed for up to 3 terms.

e) The Chair will appoint one of the members of the UWA HREC as Deputy Chair. The Deputy Chair shall hold office at the Chair's discretion.

f) The Deputy Chair will preside over any meeting of the UWA HREC the Chair does not attend and may act in the place of the Chair in any other capacity of the Chair when requested to do so by the Chair.

g) Where both the Chair and the Deputy Chair are unable to attend a meeting of the Ethics Committee the Chair will appoint one of the members present at that meeting to preside over that meeting as Chair.

7. Operations

7.1 Procedures

a) The UWA HREC will perform their functions by adopting the requirements outlined in the National Statement and according to UWA HREC constitution and relevant UWA policies. These procedures will be reviewed periodically and amended and updated as necessary.

b) All UWA HREC members and researchers will have access to these policies and procedures.

c) In carrying out its functions the UWA HREC shall:

   i. ensure their enquiries of the researcher will be made in a spirit of courtesy and support, to develop mutual respect and a sense of partnership in the development of sound ethical practice;

   ii. provide the decisions of the UWA HREC in writing and within a reasonable timeframe to the researchers;

7.2 Meetings

a) The UWA HREC meetings are scheduled fortnightly, meeting 22 times in the calendar year.

b) The UWA HREC is divided into two sub-committees (red HREC and yellow HREC) with each committee meeting 11 times in the calendar year.

c) HREC meetings are conducted in person, on the UWA campus.

d) Meetings may be conducted online using Microsoft Teams in some circumstances.

e) Special "out of session" meetings may be organised as required.

f) The agenda and supporting papers shall be sent to UWA HREC members at least 10 working days before a meeting.

g) Member comments are entered into the Research Online Application Portal (ROAP) prior to the meeting and details of reviews are recorded in ROAP.

h) A quorum consists of the eight (8) members required to fulfil the minimum membership requirements as outlined in the National Statement.

i) HREC members appointed to one of the two sub-committees, may, on occasion serve on the other to ensure minimum membership is maintained.

a) If the eight core members are not present the Chair must be satisfied that these members have received all the relevant papers and have had the opportunity to contribute their views and that these have been received and

considered before a final decision is made (as per Section 5.2.30 of the National Statement).

a) In discharging its responsibilities, the HREC may seek the advice of such experts as it chooses.

b) The HREC may invite researchers, and researchers may request, to be present for discussion of their proposed research project.

c) HREC activity will be reported quarterly to the DVCR.

7.3 Declaration of Interest

a) HREC members must declare associations that may give rise to any actual, potential or perceived conflict of interest at the commencement of the meeting.

b) Members may not review and approve their own research. In such cases, the member must declare a conflict of interest and be excused from review of that application.

c) The meetings minutes will include declarations of conflict of interest and the decision of the HREC on how the conflict of interest is managed.

7.4 Confidentiality

a) The agenda and minutes of meetings, applications, supporting documentation and correspondences are all treated confidentially.

b) 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).

c) 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.

7.5 Decision Making

a) Decisions of the UWA HREC will only be made after members from each of the member categories have had an opportunity to contribute their views during or prior to the decision-making process. Members unable to attend the meeting will be asked to forward comments to the REC office prior to the meeting.

b) On considering research projects, members should deliberate on the values and principles of the National Statement, exercise their judgement, and appreciate the context of the research proposed. Decisions should be reached by general agreement; they need not be unanimous.

c) The HREC decision on an individual research project may be the following:

- Approve the application as being ethically acceptable
- Request modification or further information/clarification
- Seek further advice from external expert reviewer(s)
- Reject the application.

d) When the HREC determines that modifications are required prior to a research project being approved, the assessment of such modifications can be assigned to a HREC delegate, being the Chair, another HREC member or a member of the REC office. Decisions made by HREC delegates must be ratified by the committee at its next meeting.

e) Minutes of the UWA HREC meeting are ratified as a true record of proceedings and decisions taken (or amended) by the UWA HREC at its subsequent meeting. The HREC Chair will consider and authorise actions arising from a draft record of a meeting in advance of this ratification to enable timely communication with researchers.

7.6 Suspension or withdrawal of ethical approval

a) The UWA HREC may suspend or withdraw ethical approval if a project is not being, or cannot be, conducted in accordance with the approved protocol.

b) The UWA HREC will inform the Chief Investigator and the relevant institution or organisation of such a withdrawal and recommend to the institution or organisation that the project be discontinued, suspended, or that other necessary steps be taken.

7.7 Records

a) The Office of Research Director is responsible for the provision of facilities and staff sufficient to support the functions of the UWA HREC.

b) The REC office is responsible for preparing and maintaining records of the UWA HREC's activities including agendas and minutes of all meetings of the UWA HREC in line with the UWA HREC Constitution.

c) The REC office will maintain a database of all applications received and reviewed in accordance with the National Statement.

d) Records will be managed as per the University requirements.

7.8 Delegations

a) The UWA HREC may delegate any or all its decision-making power to the Chair to enable expedited review and decision making through:

   i. specifying the situation where this occurs on a case-by-case basis (e.g., final approval following provisional approval by the UWA HREC) or

   ii. in relation to a category of types of decisions (e.g., amendments).

b) When enacting the delegation, the Chair must act in a way consistent with the principle that HREC decision making encompasses the diversity of perspectives provided by the composition of the UWA HREC and in accordance with the guidance of the National Statement.

c) The delegation may include signing relevant documentation on behalf of the UWA HREC.

d) Decisions made by the Chair under delegated authority are ratified by the UWA HREC at the subsequent meeting.

e) The Chair may delegate the Manager, Research Ethics and Compliance (REC), Senior Ethics Officer (SEO) or other members of the REC office, to carry out administrative tasks and make decisions on behalf of the UWA HREC.

7.9 Expedited Review

a) The review of modifications and renewals of approved research protocols may be through an expedited review process between scheduled meetings at the discretion of the Chair or delegate.

b) The Chair or delegate may seek advice from other UWA HREC members or a person with relevant expertise, as appropriate, before reaching a decision.

c) When approval is granted, such approval will be added to the agenda for the next meeting for ratification.

8. Complaints process

a) Complaints concerning the HREC's review process should be made in writing, receipted by the REC Office and forwarded to the Chair for consideration.

b) In the event that the Chair cannot resolve the complaint, the Associate Director, Research Ethics and Integrity will conduct an investigation, which may or may not require the assistance of the UWA HREC, depending on the nature of the complaint.

c) Where the complaint cannot be readily resolved by the Associate Director, Research Ethics and Integrity, the complaint may be referred to an assessor who is independent of UWA.

9. Review of Terms of Reference

a) These Terms of Reference shall be amended on the recommendation and approval of the DVCR.

b) Updates should be annually in response to evaluation of the committee. The UWA HREC Chair or Manager REC shall be responsible for initiating this process.

c) Revision history

Version	Approval date	Effective date	Extent of revision
1.0	August 2025	August 2025	First release of UWA HREC Terms of Refence. Previously a Standard Operating Procedure document.