

Terms of Reference: Federation University Australia Human Research Ethics Committee

1. Purpose

The Human Research Ethics Committee (HREC) of Federation University Australia (FUA) is established to ensure all human research conducted under the auspices of FUA complies with the [National Statement on Ethical Conduct in Human Research \(2025\)](#). The HREC provides independent, competent and timely ethics review to protect and promote the rights, welfare, dignity and safety of people participating in research activities.

The Terms of Reference incorporate all requirements set out in Section 5.1.29 of the National Statement.

2. Scope

These Terms of Reference apply to HREC review of:

- All human research conducted by staff and students of FUA
- All human research conducted on FUA premises or using FUA resources

Human research includes the use of biospecimens, information or data (quantitative or qualitative) from people, whether they are aware of their participation in the research or not. FUA may choose to make exempt certain human research activities only where permitted by the National Statement and as described within the [Research Ethics and Institutional Biosafety Procedure \(RS2096\)](#).

Only applications from current staff will be reviewed by the HREC. The Chief Investigator named on the application will hold responsibility for the project (as per [Research Ethics and Institutional Biosafety Procedure \(RS2096\)](#)) and must be a current staff member of FUA.

The HREC does not accept applications from parties external to FUA. No fees are charged for review of applications.

3. Authority and reporting

The HREC is established under the authority of the Pro Vice-Chancellor (Research and Innovation) and reports annually through the Research Committee to the Academic Board.

To fulfill registration requirements, the University reports annually to the National Health and Medical Research Council on activity and assurance.

4. Responsibilities

Ethics review: Determine whether proposals meet the National Statement's requirements, including (but not limited to) that risks are justified by the potential benefits of the research, and suitable consent is obtained from participants.

Monitoring: Monitor approved research via annual and final reports; audit projects as required; and require researchers to report incidents or unexpected issues associated with their approved research projects promptly.

Decisions: Make decisions on applications, amendments and monitoring matters; require modification, suspend or withdraw approval to protect participants where necessary.

Records and reporting: Maintain meeting records, decisions and correspondence; report annually to the Academic Board via the Research Committee and to the NHMRC.

Advisory and education: Advise FUA on human research ethics requirements and their application to the research context, and promote best practice.

5. Membership

The HREC will strive for diversity in its membership. At least one-third of members will be external to FUA. It comprises at least eight members meeting the minimum categories required by the National Statement, including:

- A Chair
- At least two community members
- A professional care member
- A member with current research experience
- A member with a pastoral care role
- A lawyer

A Deputy Chair will be appointed from among the HREC membership. When acting as Chair, the member's normal category must be filled by another HREC member. No individual may represent more than one membership category at any given meeting.

For research involving Aboriginal and Torres Strait Islander peoples, the HREC will include or draw upon members with appropriate cultural knowledge or expertise.

Members are appointed by the Pro Vice-Chancellor (Research and Innovation) for three-year renewable terms. Members are appointed as individuals, not as representatives of groups or organisational units. Members who are staff or students of FUA will not receive remuneration; members external to the University will receive reimbursement for costs incurred as per the [Research Compliance Committees External Members Allowance Procedure \(RS2063\)](#).

Appointment letters will specify responsibilities, term, category of representation, confidentiality obligations, disclosure of interests and legal protections.

6. Delegations

- Higher Risk research must be reviewed and approved by the HREC. A Low Risk Human Ethics Committee (LRHEC) operates as a subcommittee, with delegated authority to review and approve Lower Risk applications. As described within the National Statement (Chapter 2.1), risk exists on a continuum but to determine the proportionate level of review and oversight for each project, the use of risk categories is useful:
 - **Lower risk:** There is no risk of harm, potential for inconvenience, burden or discomfort for participants.
 - **Higher risk:** There is a risk of harm (i.e. more than discomfort) for participants (or their communities or society).

The HREC may endorse external approvals for collaborative projects through the Externally Approved Application process. No research may commence without written approval from the relevant committee.

7. Quorum and meetings

The HREC usually meets monthly, February to December. Members may attend via approved remote means. Decisions may only be made when minimum membership requirements are met in accordance with the HREC Standard Operating Procedure. Additional members or members from a membership pool may participate to ensure minimum categories are met.

8. Decision making

The HREC seeks consensus but where consensus is not achieved, the Chair will decide on the outcome (usually a majority applies and dissent is recorded). The application decision outcomes align with FUA procedure and the HREC Standard Operating Procedure:

- Approved
- Approved with Comment
- Provisional Approval
- Approval Withheld
- Not Approved

The HREC may seek advice from experts external to its membership when specialised input is required. External advisors do not participate in decision making or count toward minimum membership and are bound by confidentiality.

9. Conflict of interest

Members must declare any real, potential or perceived conflict of interest. Conflicted members withdraw from consideration of the item and are not counted toward minimum membership for that item.

10. Complaints and non-compliance

Complaints about research or researchers are handled under the [Research Integrity and Misconduct Procedure \(RS1502\)](#) via the Research Integrity Office. Complaints about HREC processes are handled by the Manager, Research Ethics and Integrity, with escalation routes set out in FUA procedure. Non-compliance may lead to suspension or withdrawal of approval and notification to governance bodies as required.

11. Confidentiality

Members must maintain confidentiality regarding applications, deliberations, decisions prior to official communication and personal information. Records are retained securely by the Ethics Office.

12. Term of approval

HREC approval is valid for a maximum of five years, subject to monitoring requirements and continuing compliance.

13. Review of these terms

These Terms of Reference will be reviewed at least every three years or earlier if required by changes to the National Statement or FUA policy.