# Standard Operating Procedure: Federation University Australia Human Research Ethics Committee

## 1. Purpose

This Standard Operating Procedure (SOP) defines the processes for HREC review, approval, monitoring and oversight of human research at Federation University Australia (FUA), consistent with the National Statement on Ethical Conduct in Human Research (2025) and FUA's Research Ethics and Institutional Biosafety Procedure (RS2096).

This SOP documents, implements and publicises HREC operations as required by National Statement 5.2.1–5.2.24.

## 2. Definitions

***HREC:*** Human Research Ethics Committee.

***LRHEC:*** Low Risk Human Ethics Committee.

***Chief Investigator (CI):*** Lead researcher, holds responsibility for the project (as per the Research Ethics and Institutional Biosafety Procedure).

***Risk levels:*** Risk exists on a continuum, with broad categories applied to help understand and describe risk. The categories are Lower Risk (risk of no more than discomfort) and Higher Risk (risk of harm, i.e. more than discomfort), as described in the National Statement (Chapter 2.1).

***Meeting papers:*** The complete set of application materials and agenda papers distributed for a scheduled meeting.

***External advisor:*** A non-member with relevant expertise invited to advise the HREC on a topic or application; does not deliberate or decide on outcomes.

***Observer:*** A person invited to observe a meeting; does not deliberate or decide on outcomes.

## 3. Governance and roles

***HREC:*** Reviews Higher Risk applications, and applications that propose to use an opt-out approach or waive the requirement for consent where participants' personal information will be collected or used; may review Lower Risk applications when required; decides on approvals,

amendments and monitoring; reports to Academic Board (via Research Committee) and the NHMRC; and is registered with the NHMRC.

***LRHEC:*** Is a subcommittee of the HREC; reviews Lower Risk applications; holds delegated approval authority; and operates in parallel with the HREC.

***Ethics Office***: Provides administrative support and regulatory advice; maintains records; issues notifications; and coordinates reporting and audits.

# 4. Submission and triage

## 4.1. Submission

CIs submit applications to the Ethics Office using the current application template. Applications should include all supporting materials. No research may begin without written approval from the HREC or LRHEC.

## 4.2. Triage and allocation

The Ethics Office screens each application for completeness and clarity, and triages risk level for allocation to the appropriate review pathway.

***Lower Risk***, includes:

- *Minimal Risk:* No risk of harm or discomfort; potential for minor burden or inconvenience
- *Low Risk:* No risk of harm; risk of discomfort (with or without foreseeable burden)

***Higher Risk***, includes:

- *Greater than Low Risk:* Risk of harm (with or without foreseeable burden)
- *High Risk:* Risk of significant harm (with or without foreseeable burden)

Where an application is incomplete or unclear, the HREC or LRHEC will be unable to determine if National Statement requirements have been met. The Ethics Office will return incomplete or unclear applications to the CI noting the information that is missing or unclear. Submission of complete and clear applications supports committee decision making and reduces the likelihood of extensive revision requests and multiple rounds of review.

Risk can:

- Be associated with the conduct of the research or the research outcomes
- Be to individual research participants, or to groups, communities or other non-participants (e.g. family members of the participants)
- Arise from the research context, specific attributes or characteristics of the participants, or interaction between the research context and the attributes or characteristics of the participants

The application form lists research contexts and participant characteristics that may give rise to increased risk of harm. CIs should assess the risk and indicate risk level (Higher or Lower). Where a listed item is present in the research project, the application will generally be considered Higher Risk. If, in such cases, the CI assesses the project as Lower Risk (i.e. risk of

no more than discomfort) they should include a clear rationale. The Ethics Office considers this information when triaging and deciding on risk level, and may seek advice from the Chair if the risk level is unclear. The Ethics Office will:

- Confirm the risk level
- Allocate the application to the next available meeting of the appropriate committee
- Notify the CI

# 5. HREC review process

## 5.1. Review standards

The HREC considers whether applications meet the requirements of the National Statement, including (but not limited to): risk–benefit ratio, participant welfare, consent, privacy and data management, inclusion and respect, researcher competence and monitoring arrangements.

## 5.2. Minimum categories and exchange of views

(a) Meetings are arranged to enable attendance of all minimum membership categories, in person or via available technology.

(b) Where a minimum category member cannot attend, the Chair must be satisfied that the views of a member representing that category have been received and considered by those participating before a decision is made.

(c) Decisions about whether a proposal meets National Statement requirements are informed by an exchange of opinions from participating members.

## 5.3. Attendance of people other than members

(a) Researchers may, at the Chair's discretion, attend for discussion of their application but not for deliberations or decision making.

(b) The HREC may seek advice from external advisors to assist consideration. External advisors are bound by confidentiality; any interests must be disclosed and conflicts managed. They do not take part in deliberations or decisions and are not counted toward quorum.

(c) Observers may be invited to attend. They are bound by confidentiality and disclosure of interests requirements. They do not take part in deliberations or decisions and are not counted toward quorum.

## 5.4. Decision making

The HREC seeks consensus. If consensus is not possible, the Chair will confirm the outcome (usually reflecting the majority view) and dissent will be recorded in the minutes.

# 6. Operating procedures

## 6.1. Frequency of meetings

The HREC meets monthly, usually from February to December. Additional meetings may be convened where necessary.

## 6.2. Attendance at meetings

Members are expected to attend scheduled meetings. Where unavailable, members provide written comments in advance, and the Chair ensures these are shared and considered so as to meet minimum membership requirements.

## 6.3. Conduct of meetings

Meetings are chaired by the Chair (or Deputy Chair by delegation in the Chair's absence). The Chair manages order of business, encourages balanced debate, ensures exchange of views and confirms actions and decisions before close.

## 6.4. Agendas and minutes

The Ethics Office prepares agendas and minutes. Minutes are endorsed at the next meeting. Minutes record attendance, declarations of interest, summaries of deliberations, decisions, dissents and actions.

## 6.5. Distribution of papers

Meeting papers are distributed sufficiently in advance to allow members to be fully informed, usually at least five working days before the meeting unless an urgent meeting is convened.

## 6.6. Timely consideration of applications

Applications are considered at the next available meeting, consistent with published closing dates, the risk level of the application and the number of applications scheduled for review relative to adequate resourcing and committee workload so as not to compromise the quality of review. Out-of-session review is available only in exceptional circumstances and is subject to HREC quorum requirements.

## 6.7. Conflicts of interest: disclosure and management

Members disclose any interests to the Chair in advance or at the meeting. Conflicted members withdraw for that item. Disclosures and management are minuted.

## 6.8. Confidentiality

Applications, papers, deliberations and decisions are confidential. Members, external advisors and observers must keep all such information confidential and handle documents securely.

## 6.9. Prompt notification of decisions

The Ethics Office issues written decision outcomes and revision requests to the CI promptly, usually within five working days.

## 6.10. Communication with researchers

Communication may be face-to-face, by telephone or in writing (including electronic formats). Where communications involve the Ethics Office, they are documented and retained by the Ethics Office.

## 6.11. Record keeping

Records are maintained in accordance with Section 16 of this SOP and the National Statement (5.2.15–5.2.20).

## 6.12. Monitoring of approved research

Monitoring comprises annual reports, final reports, random or targeted monitoring and any additional mechanisms specified at approval, in accordance with Section 13 of this SOP.

## 6.13. Adverse events: reporting and handling

Serious or unexpected adverse events and unforeseen issues are reported immediately via the Incident Report process. The HREC may note the event, with or without requesting amendment, increased monitoring, suspension or withdrawal of approval.

## 6.14. Complaints: receiving and handling

Complaints are received by the Ethics Office and managed as per Section 15 of this SOP.

## 6.15. Suspension or withdrawal of approval

Where the HREC determines that approval should be suspended or withdrawn, the Ethics Office will advise the relevant institutional committee or officer in writing. Only the authorising institution has authority to instruct a researcher to suspend or cease a research project. Where approval is suspended, the institution must ensure that the researcher promptly suspends the research and makes arrangements to meet the needs of participants. Continuation may only occur where the institution authorises it on advice from the HREC that continuation would not compromise participants' welfare.

## 6.16. Attendance of non-members at meetings

Procedures for researchers, external advisors and observers are set out at 5.3 of this SOP. All non-members are bound by confidentiality and conflict-of-interest requirements.

# 7. Application decision outcomes

The HREC and LRHEC may issue the following outcomes:

***Approved:*** The project meets the requirements of the National Statement and research activities may begin.

***Approved with comment:*** The project meets the requirements of the National Statement and research activities may begin. Applicants should note and address comments as appropriate.

***Provisional approval:*** Revisions are required for the project to meet the requirements of the National Statement. Revisions are unlikely to alter the overall risk–benefit profile. The CI must

provide a point-by-point response and revised documents to the Ethics Office. Revisions may be reviewed and approved by the Chair or Deputy Chair outside of a meeting. The Chair or Deputy Chair may seek input from other members or advice from experts.

***Approval withheld:*** Revisions are required for the project to meet the requirements of the National Statement. Revisions are extensive or likely to alter the overall risk–benefit profile. The CI must provide a point-by-point response and revised documents to the Ethics Office. Revisions will be reviewed and approved by the HREC at the next available meeting.

***Not approved:*** The project does not meet the requirements of the National Statement and can not proceed in its current form. A new application may be submitted.

Suspension or withdrawal of approval may occur (see 6.15 of this SOP). These are not application outcomes at initial review.

# 8. Communication of decisions

Decisions are communicated in writing by the Ethics Office. Where rejecting, withdrawing approval or requesting revisions, the written outcome cites the relevant provisions of the National Statement or FUA policy that underpin the decision. Written approvals and rejections include an explicit statement that the proposal meets or does not meet the requirements of the National Statement.

Recruitment, data collection or analysis of identifiable data must not commence prior to written approval. Conducting research without appropriate approvals or contrary to the conditions of an approval may constitute a breach of the Australian Code for the Responsible Conduct of Research.

# 9. Out-of-session review

Out-of-session reviews are available only under exceptional or extenuating circumstances, at the discretion of the Chair. Missed submission deadlines do not qualify. For Higher Risk applications, minimum membership requirements must be achieved for a valid outcome, which may limit the feasibility of out-of-session review.

# 10. Amendments to approved projects

CIs must submit a Request for Amendment for any change to recruitment, methods, consent, materials, sites, personnel or factors affecting risk. Amendment documents (including the current approved application) must clearly show tracked changes. Minor amendments may be approved by the Chair or Deputy Chair; major amendments must return to a quorate HREC for review.

***Minor amendment:*** The amendment is unlikely to alter the overall risk–benefit profile.

***Major amendment:*** The amendment is extensive, there have been multiple amendments over time, or the amendment will likely alter the overall risk–benefit profile.

# 11. Delegation

The HREC may delegate certain actions to the Chair, one or more members, a subcommittee or administrative officers from the Ethics Office. Delegated actions, usually occurring out-of-session, are not decisions of the HREC unless ratified. Examples include review of revisions to provisionally approved applications, review of minor amendments and specified monitoring activities.

# 12. Projects approved by an external HREC

Where FUA staff or students conduct research that has already received approval from an external HREC or an equivalent non-HREC body, and that approval meets the requirements of the National Statement, duplicate review by the FUA HREC or LRHEC is not required. In such cases, the HREC Chair or Deputy Chair may endorse the external approval through the Externally Approved Application process.

Where a project has been reviewed and approved outside Australia or under requirements that differ from the National Statement, the Chair or Deputy Chair may accept the Externally Approved Application if satisfied that the external review process aligns with the principles and requirements of the National Statement. To assist in this determination, researchers must provide information outlining the external review process and how it corresponds to the National Statement's requirements. Where alignment with the National Statement cannot be determined, the CI should submit a new application.

# 13. Monitoring, reports and audits

## 13.1. Monitoring

Monitoring is conducted in accordance with the National Statement and this SOP (see also 6.12).

## 13.2. Annual and final reports

Annual reports are required for all active projects. Non-submission may lead to suspension or withdrawal of approval.

Final reports are due within one month of project completion or discontinuation. They should include outcomes, data retention and disposal, and compliance statements.

## 13.3. Random monitoring and audits

The HREC may conduct random monitoring; researchers must provide requested documents or evidence.

# 14. Incidents, adverse events and unexpected issues

CIs must promptly report serious or unexpected adverse effects on participants, unforeseen issues that increase risk, and protocol breaches, using FUA's Incident Report process. The HREC may require additional monitoring, amendment, suspension or withdrawal.

# 15. Complaints and appeals

## 15.1. Complaints about research conduct

Managed under FUA's Research Integrity and Misconduct Procedure (RS1502) via the Research Integrity Office.

## 15.2. Complaints about HREC processes or decisions

Managed under FUA's Research Ethics and Institutional Biosafety Procedure (RS2096) via the Ethics Office.

# 16. Documentation and record keeping

## 16.1. Documentation

The Ethics Office maintains agendas, minutes, decisions, correspondence, applications, amendments, reports, monitoring and audit records, retained per institutional and legislative requirements.

## 16.2. Documents requiring review and approval

Documents intended for use in the conduct of a research project must be reviewed and approved by the HREC, including all documents and other material used to recruit potential research participants.

Application forms are considered to be an official 'project document' requiring approval unless there is a formal protocol supporting the application.

## 16.3. Complete records

The Ethics Office maintains a complete record of applications reviewed, including: institutions covered by approvals; project ID; project title; CI and investigator names; correspondence; outcome decisions for new and amended applications; any conditions of approval; approval duration; proposed completion date; other review bodies' opinions where these have informed committee deliberations; monitoring mechanisms; and any privacy-related legislative assessments. All applications, approved documentation and correspondence are retained in accordance with applicable legislation and FUA retention schedules.

# 17. Member responsibilities and conduct

## 17.1. Member responsibility for ethical assessment

Each member is responsible for deciding whether, in their judgement, a proposal meets National Statement requirements and is ethically acceptable.

## 17.2. Training and participation

Members complete induction and remain familiar with the National Statement and relevant guidance. Members prepare for and attend meetings or provide written comments if unavailable, consistent with institutional policies. Members participate in continuing education in research ethics at least every three years, or more frequently where provided by the institution.

## 17.3. Confidentiality

Members comply with institutional confidentiality protocols covering interactions with other members, administrators and researchers, and all proposal reviews and discussions.

## 17.4. Conflicts of interest

Members disclose any interests that may constitute an actual or potential conflict, including financial or other interests or affiliations that may affect any research before the HREC.

# 18. Approval period

Maximum approval duration is five years, after which a new application is required.

# 19. Indigenous research

Research involving Aboriginal and Torres Strait Islander peoples must comply with the AIATSIS Code of Ethics and related national guidance as is required by the National Statement. The CI should submit an attachment to their application describing how the principles and responsibilities of the AIATSIS Code have been incorporated into the research design and are met.

# 20. Review of this SOP

This SOP will be reviewed at least every three years, or earlier following changes to the National Statement or FUA policy or procedure.