

Swinburne University of Technology HREC SOP

1. Purpose

1.1 This document outlines Swinburne's standard operating procedures associated with ethics review and is to be read in conjunction with the [Swinburne University Human Research Ethics Terms of Reference](#) and the [National Statement on Ethical Conduct in Human Research 2025](#) (National Statement) and the [Australian Code for the Responsible Conduct of Research \(2018\)](#).

2. Scope and application

2.1 These procedures apply to all staff members and students who conduct human research under the auspices of Swinburne University and its campuses. They also apply to the Swinburne University Human Research Ethics Committee (SUHREC) and all staff involved in the ethics review of proposed research and related protocols.

2.2 SUHREC does not provide ethics reviews for external researchers or organisations.

3. Human Research Ethics Committee

3.1 The Swinburne University Human Research Ethics Committee (SUHREC) has overall responsibility for review of human research ethics applications within the University.

3.2 The HREC Terms of Reference and these Standard Operating Procedures have been developed in accordance with the National Statement.

3.3 The HREC plays an important role in the University's human research ethics arrangements, but is not solely responsible for the efficient, timely and quality operation of those arrangements as this is also a key function of the Office of Research Ethics, Integrity, Biosafety and Governance (REIGB).

3.4 Membership categories of SUHREC comply with the requirements of Section 5.1.30 of NS (2025), namely:

- (a) a Chairperson
- (b) at least two community members
- (c) at least one professional care members
- (d) at least one pastoral/spiritual care member
- (e) at least one lawyer
- (f) at least two researchers.

More than the minimum number of members required in each category may be appointed to ensure a pool of members are available.

3.5 Swinburne Research provides an honorarium payment to external SUHREC members in recognition of their expertise, time, and contribution to Committee business.

4. Ethics review pathways

4.1 Human research activities must not commence until written confirmation of ethics approval has been received. In addition to ethics approval, a project may be subject to other internal or external approvals before human research can commence (e.g. research governance/site specific authorisation approval).

4.2 Ethics approval is required for the time that participant recruitment and data collection is occurring. Ethics approval is granted for a maximum period of 5 years. Researchers may request a longer approval timeframe but should provide appropriate justification.

4.3 Chief Investigators (CIs) must be staff members, not students, adjunct staff or external researchers.

4.4 Applications must be accompanied by other relevant documents, such as research participant information statements, consent forms, data collection tools, evidence of research merit, and letters of endorsement. Where relevant, the inclusion of these attachments will be prompted by the on-line ethics application form.

4.5 Applications requiring full ethics review must be submitted in line with published due dates for review at a scheduled HREC meeting. Submission and meeting dates are published on the Swinburne Ethics website.

4.6 All human research conducted under the auspices of the University must be submitted to the Ethics Office for ethics review via one of the below pathways.

(a) Exemption – for research that carries a lower risk to participants or the community and satisfies one or more of the conditions outlined in section 5.1.17 of the National Statement. Applicants must submit a human research ethics exemption request (and relevant attachments) for review.

(b) Expedited ethics review - for research that has already been granted ethics approval by another NHMRC-registered or NHMRC certified HREC. Applicants must submit an application in ERM, along with the application documentation approved by the primary HREC and evidence of their ethics approval for review by the SUHREC Chairperson.

(c) Full ethics review (SUHREC or SHESC) - where the National Statement specifies that the category of research must be reviewed by a HREC, applicants must submit a human research ethics application (and relevant attachments) for review by SUHREC. For lower risk research, the review can be conducted by a SUHREC Human Ethics Subcommittee (SHESC).

5. Meeting procedures

5.1 SUHREC meetings are held monthly via Teams (12 meetings per year).

5.2 Members should attend for the duration of each meeting, unless they have a conflict of interest in which case they should absent themselves during discussion of that application. If a member is unable to attend the meeting itself they are invited to provide review comments prior to the meeting and these comments will be discussed by the HREC on the meeting day. Attendance of observers and guests at SUHREC meetings is at the discretion of the Chairperson.

5.3 Meetings are conducted following the agenda and led by the SUHREC Chairperson. Debate is informal and decision reached by consensus. Each application is reviewed by at least three members allocated to lead the review and the Chairperson, however all members are invited to review and comment on all applications.

5.4 Deliberations are based on the National Statement and relevant regulations consistent with SUHREC's constitution. The Chairperson should determine whether the Committee holds the appropriate collective expertise to review certain types of projects. In accordance with NS 5.1.38, SUHREC can call on additional subject matter experts for review of applications. SUHREC may approve a research proposal, request revisions or clarification before granting approval, reject the proposal, or withdraw approval where ethical requirements are no longer met. Decision making is normally by consensus (not necessarily unanimous). If consensus cannot be reached, the Chairperson may call for a vote.

5.5 Members are advised on appointment to the committee that all applications and deliberations are confidential.

6. Agendas and minutes

6.1 SUHREC uses the University's online ethics management system, ERM (Ethics Review Manager) to prepare, circulate and retain meeting agendas and minutes in a secure and auditable manner. Agendas are prepared by the Secretary and usually made available 9 working days prior to the SUHREC meeting. Meeting decisions and outcomes are recorded in ERM, with minutes providing an accurate record of matters considered, decisions reached, any declared conflicts of interest, and conditions or

actions arising. Endorsed minutes are retained as the official Committee record and stored securely in ERM.

6.2 Within three working days of endorsement of the minutes, the Secretary distributes outcomes to applicants; on receiving responses, assesses them against conditions and either updates approval status or refers full documentation to the Chairperson and/or nominated SUHREC members for decision.

7. Communication with researchers

7.1 Review outcomes are communicated to researchers via email through ERM.

7.2 Researchers can contact the Ethics Office via email or telephone, or can meet with Ethics Office staff in person or via Teams to discuss review outcomes.

8. Modifications to approved projects

8.1 Modifications to ethics approved projects require written ethics approval prior to implementing the changes. Modifications must be granted ethics approval via one of the pathways outlined in section 4 of these procedures.

8.2 A modification can be requested via the modification sub-form in ERM. Revised versions of all relevant application documentation must also be included. All changes should be clearly tracked (using track changes) or highlighted.

8.3 Modifications requiring full SUHREC review must be submitted in line with published due dates for review at a scheduled HREC meeting. Other modifications can be submitted at any time and will usually be reviewed within 5 working days.

8.4 If a modification has already been granted ethics approval by another NHMRC-registered HREC and the project received an 'Expedited Review' approval at Swinburne the modification must be submitted in ERM for review. In addition to the modification sub-form, applicants must also attach the application documentation considered by the lead HREC and evidence of their ethics approval.

8.5 The amended aspects of the project must not commence until written ethics approval has been granted.

9. Projects involving more than one institution or HREC

9.1 Even if the research project has been reviewed and approved by another HREC, Swinburne ethics approval must also be granted. Such applications are reviewed via the Expedited Review pathway. In the case where the original ethics approval has expired, Swinburne Ethics approval needs to be granted via one of the other ethics review pathways outlined in section 5 of these procedures.

10. Monitoring human research activities

10.1 Researchers must submit annual and final reports using the Report forms in ERM. Annual reports are due on the anniversary of the ethics approval date and Final Reports are due by the end date of the ethics approval period (or earlier if the project is completed prior to that date).

10.2 For projects approved via the Expedited Review pathway, applicants must submit a copy of the report submitted to the lead ethical review body and evidence of their approval as soon as practicable. If this is not possible, the Swinburne University report form must be submitted instead.

10.3 Reports are reviewed by the Ethics Office unless concerns are raised, in which case a HREC Chairperson or HREC review is arranged.

10.4 Compliance may also be monitored by any other means deemed necessary or appropriate, such as random audits or more frequent reporting requirements.

10.5 SUHREC reports and makes recommendations to the Deputy Vice Chancellor Research. It provides an annual report to University Senate via the Research Policy and Quality Committee and an annual report to the National Health and Medical Research Council (NHMRC).

11. Adverse events

11.1 Adverse events must be reported to the Ethics Office as soon as practicable using the Adverse Event report form in ERM. In cases where researchers are unable to complete the form immediately, every effort must be made to report the event via other means, such as phone or email, until such time the form can be submitted.

11.2 Adverse event reports are reviewed by the HREC Chairperson and may be referred for further advice if needed.

11.3 For projects approved via the Expedited Review pathway, applicants must submit a copy of the adverse event report submitted to the lead HREC and evidence of their approval for the report for review by the Ethics Office.

12. Complaints and non-compliance

12.1 Complaints and non-compliance are managed in accordance with the Australian Code for the Responsible Conduct of Research (the Code), the National Statement and where appropriate, other university policies (e.g. HDR student policy).

12.2 Where complaints are made about projects that would normally require ethics approval, the SUHREC Chairperson is authorised to review the matter. The Chairperson can refer such complaints to the HREC, to an external ethical review body, to the Ethics

Office, or to the department responsible for the governance of the project, as appropriate. When complaints relate to activities that have unexpected adverse effects, ethics approval can be withdrawn or suspended.

12.3 Any non-compliance with ethics review or HREC decisions must be reported to the HREC Chairperson. The Chairperson considers appropriate actions and can refer the non-compliance to SUHREC, external ethical review body, Swinburne Research, or department responsible for the governance of the project as appropriate.

12.4 Where complaints concerning the HREC review of a human research application, amendment, or report cannot be resolved by communication between the complainant and the HREC, the Manager, Research Integrity is authorised to receive complaints. The Office of Research Ethics, Integrity, Governance and Biosafety considers the complaint and may seek further advice internally or externally as appropriate. The Manager, Research Integrity respects the privacy and confidentiality of the complainant and only engages other parties on a need-to-know basis.

12.5 The ultimate decision regarding the ethical acceptability of human research lies with the HREC and cannot be overridden. Researchers who disagree with a HREC decision are welcome to provide their reasons to the HREC Chairperson and resubmit a revised application for further ethics review. Researchers should be assured that submitting complaints about the merit of a HREC decision can be done so confidentially and does not affect any future ethics applications.

Definitions

Term	Definition
ERM (Ethics Review Manager)	The online platform used for the submission, review and management of ethics applications.
Ethics review	The review of proposed research by an HREC or other body regarding its adherence to the <i>National Statement on Ethical Conduct in Human Research</i> and Human Research Ethics Guidelines.
Ethical values and principles	The values and principles that the <i>National Statement on Ethical Conduct in Human Research</i> and the <i>Australian Code for the Responsible Conduct of Research</i> state need to be addressed in the design, ethical review and conduct of human research.
HREC	Human Research Ethics Committee

Human research	Research conducted with or about people or their data or tissue.
Lower risk (research)	Research in which there is no risk of harm, but in which there is risk of discomfort and in which there may also be a foreseeable burden (low risk research) OR research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience (minimal risk research).
National Statement	National Statement on Ethical Conduct for Human Research (2025)
Research	As defined in the Australian Code for the Responsible Conduct of Research , ie. the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings.
SUHREC	Swinburne University Human Research Ethics Committee

Procedure Details

Approval	Senior Manager, Research Ethics, Integrity, Governance and Biosafety [28/05/2026]
Procedure Owner	Manager, Research Ethics
Procedure Author	Manager, Research Ethics
Status	Approved
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History

History of approval of the procedure and its amendments

Version	Date	Approved by	Change
V1.0	28/05/2026	Jane King, Senior Manager REIGB	Initial procedure release

Procedure Governance

Type	Document(s)
Linked Policy(s)	Swinburne Responsible Conduct of Research Guidelines and as updated
Supporting documents (guidelines, manuals frameworks, plans, standards)	National Statement on Ethical Conduct in Human Research (2025) Australian Code for the Responsible Conduct of Research (2018) Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities (NHMRC 2018) Keeping Research on Track II: A companion document to Ethical conduct in research with Aboriginal and Torres Strait Peoples and communities (NHMRC 2018) AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (the AIATSIS Code) (2020)
Associated policies and procedures	REIGB SOPs and Work instructions
Related legislation	Commonwealth Privacy Act 1988 Victorian Privacy and Data Protection Act 2014 Swinburne University of Technology Act 2010