

Human Research Ethics - Procedures

1. Purpose

1.1 This document outlines the procedures associated with ethics review and is to be read in conjunction with the Human Research Ethics – Governing Policy, the Human Research Ethics Guidelines and the *National Statement on Ethical Conduct in Human Research* (National Statement).

2. Scope and application

2.1 These procedures apply to all staff members and students, visiting academics, volunteers and other personnel who conduct human research under the auspices of the University. They also apply to the UniSC Human Research Ethics Committee (HREC) and all staff involved in the ethics review of proposed research and related protocols.

3. Definitions

Refer to the University's Glossary of Terms for definitions as they specifically relate to policy documents.

Ethics review: the review of proposed research by an HREC or other body regarding its adherence to the *National Statement on Ethical Conduct in Human Research* and Human Research Ethics Guidelines.

Ethical values and principles: the values and principles that the *National Statement on Ethical Conduct in Human Research* and the Code state need to be addressed in the design, ethical review and conduct of human research.

Human research: research conducted with or about people or their data or tissue..

Human Research Ethics Guidelines: a University resource for researchers that outlines the University's interpretation and implementation of the National Statement and provides a transparent policy basis for the conduct of ethics review. The guidelines are available on the Student Portal for staff and students.

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).

Research: as defined in the *Australian Code for the Responsible Conduct of Research*.

4. Human Research Ethics Committee

4.1 The UniSC Human Research Ethics Committee (HREC) is the prime body within the University that has overall responsibility for implementing the stated purpose of the Human Research Ethics - Governing Policy.

4.2 The HREC Terms of Reference and Operating Guidelines have been developed in accordance with the National Statement.

4.3 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.

5. Ethics review pathways

5.1 Human research activities must not commence until written ethics approval has been granted. In addition to ethics approval, a project may be subject to other internal or external approvals before human research can commence. For example, a safety specific risk assessment or gatekeeper approval.

5.2 Ethics approval is required for the time that participant recruitment and data collection is occurring. Ethics approval is normally granted for up to three years, unless the project is subject to a longer grant. Researchers may request a longer approval timeframe but should provide appropriate justification.

APPROVAL AUTHORITY

Deputy Vice-Chancellor (Research and Innovation)

RESPONSIBLE EXECUTIVE MEMBER

Deputy Vice-Chancellor (Research and Innovation)

DESIGNATED OFFICER

Director, Office of Research

FIRST APPROVED

16 August 2017

LAST AMENDED

7 March 2024

REVIEW DATE

22 April 2027

STATUS

Active

5.3 Generally, Chief Investigators (CIs) must be staff members, not students or external researchers. In the case where a student or external researcher has been approved as the CI by another review body and approval by the University is sought via the prior ethics review pathway, the student or external researcher may remain listed as the CI.

5.4 Generally, applications must be accompanied by other relevant documents, such as research project information sheets, 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 form or cover sheet.

5.5 Applications requiring full ethics review must be submitted in line with published due dates for review at a scheduled HREC meeting. Applications eligible for review via another pathway can be reviewed and approved at any time and will be ratified by the HREC at the next meeting.

5.6 All human research conducted under the auspices of the University must be submitted to the Office of Research 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 administrative review by the Office of Research.

(b) Prior ethics review (PR) - for research that has already been granted ethics approval by another ethical review body, applicants must submit a prior ethical review cover sheet, along with the application documentation considered by the lead ethical review body and evidence of their ethics approval for administrative review by the Office of Research.

(c) Expedited ethics review level 1 (E1) - for lower risk research with no significant ethical issues to explore, applicants must submit a human research ethics application (and relevant attachments) for review by the UniSC HREC Chairperson.

(d) Expedited ethics review level 2 (E2) - for lower risk research with some significant ethical issues that have been adequately addressed by the research design, applicants must submit a human research ethics application (and relevant attachments) for review by a panel of UniSC HREC members.

(e) Full ethics review (FR) - for research that does not qualify for any of the above pathways, or 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 the UniSC HREC.

6. Research merit

6.1 Evidence of research merit needs to be provided before ethics approval can be granted for new projects.

6.2 Research merit can be established through peer review or prior ethics approval from an appropriate body.

6.3 Evidence of peer review should be provided using the peer review checklist.

7. Amendments to approved projects

7.1 Amendments to ethics approved projects require written ethics approval. Amendments must be granted ethics approval via one of the pathways outlined in section 5 of these procedures.

7.2 The appropriate pathway will be determined by the level of risk associated with the amendment rather than the original ethics review pathway for the project.

7.3 An amendment can be requested via the amendment request cover sheet. Revised versions of all relevant application documentation will also be required. All changes should be clearly tracked (using track changes) or highlighted.

7.4 Amendments requiring full ethics review must be submitted in line with published due dates for review at a scheduled HREC meeting. Amendments eligible for review via another pathway can be reviewed and approved at any time and will be ratified by the HREC at the next meeting.

7.5 If an amendment has already been granted ethics approval by another HREC, the amendment must be submitted to the Office of Research for review via the prior review pathway described in section 5 above. Applicants must submit an amendment request cover sheet along with the application documentation considered by the lead ethical review body and evidence of their ethics approval.

7.6 The amended protocol must not commence until written ethics approval has been granted.

8. Projects involving more than one institution or HREC

8.1 Where staff members or students are formally involved in collaborative human research, ethics approval must be granted via one of the ethics review pathways listed in section 5 of these procedures.

8.2 Even if the research project has been reviewed and approved by another ethical review body, UniSC ethics approval must also be granted. Such applications are reviewed via the prior ethics review pathway. In the case where the original ethics review was not in line with the requirements of the National Statement or the ethical review body that previously granted approval will no longer be involved in monitoring the project, UniSC ethics approval needs to be granted via one of the other ethics review pathways outlined in section 5 of these procedures.

9. Monitoring human research activities

9.1 Researchers must submit progress reports using the progress report form, unless the project was approved via the exemption pathway.

9.2 For projects approved via the prior 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 UniSC progress form must be submitted instead.

9.3 Reports are due from the date of ethics approval, but the HREC can request these on a more frequent basis, if required, or as soon as data collection is complete, ethics approval has expired, or the project has been discontinued.

9.4 Reports are reviewed by the Office of Research unless concerns are raised, in which case a HREC Chair or HREC review is arranged.

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

10. Standard operating procedures

10.1 Standard operating procedures (SOP) for processes likely to be relevant to more than one ethics application must be documented and submitted to the HREC for approval. New SOPs and amendments to approved SOPs must be approved by the HREC before implementation.

10.2 Once approved, SOPs must be referenced in a human research ethics application. The use of a HREC approved SOP does not negate the need for human research ethics approval for each project using the SOP.

10.3 The HREC can grant a maximum three-year approval for a SOP to be used in human research activities. The HREC can only approve the use of a SOP in a research project when it is satisfied that each researcher or other person who implements all or part of a proposed SOP has the necessary expertise and competency to do so.

10.4 A register of approved SOPs is maintained by the Office of Research and made available to researchers.

11. Adverse events

11.1 Adverse events must be reported to the Office of Research as soon as practicable using the adverse event report form. 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 for projects originally approved by the full review or expediated pathways are reviewed by the HREC Chairperson.

11.3 For projects approved via the prior 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 Office of Research.

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 the Responsible Research Conduct – Governing Policy and Managing and Investigating Breaches of Responsible Research Conduct - Procedures.

12.2 Complaints about human research

12.2.1 Where complaints are made about projects that would normally require ethics approval, the UniSC HREC Chairperson is authorised to review the matter. The Chairperson can refer such complaints to the HREC, to an external ethical review body, to the Office of Research, 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 Non-compliance with ethics review decisions

12.3.1 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 the UniSC HREC, external ethical review body, Office of Research, or department responsible for the governance of the project as appropriate.

12.4 Complaints about HREC review process

12.4.1 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 Office of Research is authorised to receive complaints. The Office of Research considers the complaint, seeking further advice internally or externally as appropriate. The Office of Research respects the privacy and confidentiality of the complainant and only engages other parties on a need-to-know basis. If justified, the Office of Research can request that the HREC review its process in reaching its decision on a project and consider re-evaluating its original decision.

12.5 Complaints about the merit of the HREC decision

12.5.1 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.

END

RELATED DOCUMENTS

- Conflict of Interest - Governing Policy
- Managing and Investigating Breaches of Responsible Research Conduct - Procedures
- Research Data Management - Procedures
- Resolution of Complaints (Staff) - Guidelines
- Responsible Research Conduct - Governing Policy
- Risk Management - Governing Policy
- Staff Code of Conduct - Governing Policy
- Student Conduct - Governing Policy
- Working with Vulnerable People (including Child Protection) - Governing Policy

LINKED DOCUMENTS

- Human Research Ethics - Governing Policy

RELATED LEGISLATION / STANDARDS

- Australian Code for the Responsible Conduct of Research (2018)
- National Statement on Ethical Conduct in Human Research
- Ethical conduct in research with Aboriginal & Torres Strait Islander Peoples & communities: Guideline
- Human Rights Act 2019 (Qld)
- Keeping research on track II 2018