Human Research Ethics - Procedures

1. Purpose of procedures

1.1 This document outlines the procedures associated with ethical 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*.

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 USC Human Research Ethics Committee (USC HREC) and all staff involved in the ethical review of proposed research and related protocols.

3. Definitions

Please refer to the University's Glossary of Terms for policies and procedures. Terms and definitions identified below are specific to these procedures and are critical to its effectiveness.

Ethical review: the review of proposed research regarding its adherence to the *National Statement on Ethical Conduct in Human Research* andHuman 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: any research activity with or about human participants, including their data or tissue. This covers, but is not limited to, anonymous surveys, observation of public behaviour, interviews, focus groups, behavioural tests, action research, exercise testing, exploration of sensitive personal behaviour and attitudes, clinical research, and clinical trials.

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 ethical review. The guidelines are available on the Student Portal for staff and students.

National Statement: the *National Statement on Ethical Conduct in Human Research*.

Low risk: the only foreseeable risk is one of discomfort.

Negligible risk: no foreseeable risk of harm or discomfort, and any foreseeable risk is of inconvenience only.

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

The Code: the *Australian Code for the Responsible Conduct of Research*.

4. Human Research Ethics Committee

4.1 The USC 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.

APPROVAL AUTHORITY

Deputy Vice-Chancellor (Research and Innovation)

RESPONSIBLE EXECUTIVE MEMBER

Deputy Vice-Chancellor (Research and Innovation)

DESIGNATED OFFICER

Director, Office of Research

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5. Outside of scope activities

5.1 Activities that are outside the scope of the University's human research ethics arrangements do not need ethical review or approval. However, researchers may choose to request written confirmation that a specific activity is outside of scope. In such cases, researchers should complete an outside of scope request form for review by the Office of Research.

6. Ethical review pathways

6.1 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.

6.2 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.

6.3 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 ethical review pathway, the student or external researcher may remain listed as the CI.

6.4 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.

6.5 Applications requiring full ethical 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.

6.6 Except for human research activities that are out of scope, all human research conducted under the auspices of the University must be submitted to the Office of Research for ethical review via one of the below six pathways.

(a) Exemption – for negligible risk research that only involves access to existing collections of non-identifiable data or records about humans, applicants must submit a human research ethics application (and relevance attachments) for administrative review by the Office of Research.

(b) Prior ethical 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 ethical review level 1 (E1) - for research involving no more than low risk with no significant ethical issues to explore, applicants must submit a human research ethics application (and relevance attachments) for review by the USC HREC Chairperson.

(d) Expedited ethical review level 2 (E2) - for research involving no more than low risk, with some significant ethical issues that have been adequately addressed by the research design, applicants must submit a human research ethics application (and relevance attachments) for review by a panel of USC HREC members.

(e) Full ethical 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 USC HREC.

7. Research merit

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

7.2 Research merit can be established through various means, including but not limited to peer review, the award of competitive funding, confirmation of candidature by a higher degree by research student, or prior ethics approval from an appropriate body.

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

8. Amendments to approved projects

8.1 Amendments to approved projects require written ethics approval. Amendments may be granted ethics approval via one of the six pathways outlined in section 6 of these procedures.

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

8.3 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.

8.4 Amendments requiring full ethical 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.

8.5 If an amendment has already been granted ethics approval by another HREC, the amendment may be reviewed by the Office of Research via the prior review pathway described in section 8.6 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.

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

9. Projects involving more than one institution or HREC

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

9.2 If the research project has been reviewed and approved by another ethical review body, UniSC ethics approval may be granted via the prior ethical review pathway, unless the ethical 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. In these cases, UniSC ethics approval will need to be granted via one of the other ethical review pathways outlined in section 6 of these procedures.

10. Monitoring human research activities

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

10.2 For projects approved via the prior review pathway, applicants may submit a copy of the report submitted to the lead HREC and evidence of their approval instead of the progress report form.

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

10.4 Reports will be approved by the Office of Research and sent to the HREC for review, if required.

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

11. Standard operating procedures

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

11.2 Once approved, SOPs may 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.

11.3 The HREC may grant a maximum three-year approval for a SOP to be used in human research activities. The HREC will 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.

11.4 A register of approved SOPs will be maintained by the Office of Research and made available to researchers.

12. Adverse events

12.1 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.

12.2 Adverse event reports for projects originally approved by the full review or expediated pathways will be reviewed by the HREC Chairperson.

12.3 For projects approved via the prior review pathway, applicants may submit a copy of the adverse event report submitted to the lead HREC and evidence of their approval for the report instead of the adverse event report for review by the Office of Research.

13. Complaints and non-compliance

13.1 Complaints and non-compliance are managed in accordance with the Code, the National Statement and where appropriate the Responsible Research Conduct – Governing Policy and Managing and Investigating Breaches of Responsible Research Conduct - Procedures.

13.2 Complaints about human research

13.2.1 Where complaints are made about projects that would normally require ethics approval, the USC HREC Chairperson is authorised to review the matter. The Chairperson may refer such complaints to the HREC, external ethical review body, to the Office of Research, or department responsible for the governance of the project, as appropriate. If complaints relate to activities that may have unexpected adverse effects, ethics approval may be withdrawn or suspended.

13.3 Non-compliance with ethical review decisions

13.3.1 Any non-compliance with ethical review or HREC decisions should be reported to the HREC Chairperson. The Chairperson then considers appropriate actions and may refer the non-compliance to the USC HREC, external ethical review body, Office of Research, or department responsible for the governance of the project as appropriate.

13.4 Complaints about HREC review process

13.4.1 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 will consider the complaint, seeking further advice internally and/or externally as appropriate. The Office of Research will respect the privacy and confidentiality of the complainant and only engage other parties on a need to know basis. If justified, the Office of Research may request that the HREC review its process in reaching its decision on a project and consider re-evaluating its original decision.

13.5 Complaints about the merit of the HREC decision

13.5.1 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 ethical review. Researchers should be assured that submitting complaints about the merit of a HREC decision can be done so confidentially and will not affect any future ethics applications.

END

RELATED DOCUMENTS

- Conflict of Interest - Governing Policy

- Enterprise Risk Management - 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
- 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
