



HUMAN ETHICS LOW RISK COMMITTEE

Terms of Reference

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1.0 Introduction

Human Research is conducted with or about people, their data or tissue. Southern Cross University is responsible for ensuring the ethical review of human research undertaken by SCU staff, students and affiliates.

The National Statement on Ethical Conduct in Human Research (2007) – Updated 2018 [National Statement] provides for review of low-risk research outside of a Human Research Ethics Committee (HREC).

SCU has established a panel of peers based in the faculties to review research that is of low risk. Low risk research, as per the National Statement, is defined as:

- **Low risk research:** “Low risk research describes research, including some types of clinical trials, in which the only foreseeable risk is no greater than discomfort. Accordingly, research in which the risk for participants or others is greater than discomfort is not low risk research.” (NS 2023, p.13)

As per the National Statement, research that is greater than low risk, and certain other categories of research, require review by an HREC.

This document provides the Terms of Reference for the University’s LR review panel.

2.0 Responsibilities

The responsibilities of the LR Committee are to:

- 2.1 Consider the ethical implications of the projects and determine whether they comply with the with the principles of the National Statement and other relevant Acts and legislative requirements.
- 2.2 Where the projects do not meet the National Statement criteria for LR, refer them to HREC for review.
- 2.3 Facilitate ethical human research through efficient and effective review processes.
- 2.4. Monitor the progress of LR committee -approved research projects.
- 2.5 Refer potential breaches, adverse incidents, events or reactions relating to LR committee-approved projects to HREC for management.
- 2.6 Provide quarterly reports to HREC as required.

Further, the LR Committee functions on behalf of SCU to:

- 2.7 Promote understanding of ethical principles in human research by education of the University community.
- 2.8 Protect the mental and physical welfare, rights, dignity, and safety of participants of research and minimise the risk of harm arising from research studies involving humans.

3.0 Accountability

- 3.1 The LR Committee is accountable to the Deputy Vice-Chancellor (Research and Academic Capability) or their delegate.
- 3.2 Committees are established based on broad areas of research enquiry according to SCU’s Faculties and Colleges, and will reflect changes in the University governance structure.

3.2 The LR Committee operates under the guidance of, and is administratively supported by the Deputy Vice-Chancellor (Research and Academic Capability)

3.3 The LR Committee Chair or members bring to the attention of the Deputy Vice-Chancellor (Research and Academic Capability) or delegate issues of significant concern.

3.4 The LR Committee reports annually to the Deputy Vice-Chancellor (Research and Academic Capability).

4.0 Membership

Membership comprises academic representatives from Faculties and Colleges from across the University. At a minimum the LR Committee will include:

- a) HREC Chair (who is appointed by default as the LRC Chair)
- b) LRC Chair (Health)
- c) LRC Chair (Education; Law, Business and Arts; Science and Engineering; SCU Colleges; Gnibi College of Indigenous Australian Peoples)
- d) At least six reviewers drawn from research active staff (3 staff representing the Faculty of Health and 3 staff representing Education; Law, Business and Arts; Science and Engineering; SCU Colleges; Gnibi College of Indigenous Australian Peoples).

4.1 Members are required to:

4.1.1 Become familiar with the National Statement and consult other guidelines relevant to the review of specific research proposals.

4.1.2 Review applications in accordance with the National Statement.

4.1.3 Provide opinions and feedback on the ethical acceptability of research proposals in a timely manner.

4.1.4 Participate in review or monitoring of research if required.

4.1.4 On appointment, attend an induction session and observe one meeting of the LRC before formally undertaking their role as reviewer.

4.1.5 New members may be partnered with the LR Committee Chair (or nominee) during the initial stages of their tenure to assist in their learning and development, depending on their experience and expertise.

4.1.6 A requirement of continuing membership is attendance at 75% of LRC meetings in a calendar year. If members are unable to attend a meeting due to extenuating circumstances, this needs to be provided in writing to the Ethics Office in advance.

4.1.7 Attend continuing education or training programs in research ethics.

4.1.8 Disclose any actual or potential conflict of interest.

5.0 Appointments

5.1 LRC Chairs

5.1.1 The LRC Chairs are appointed by the Deputy Vice-Chancellor (Research and Academic Capability) or delegate, on recommendation from the relevant Faculty Dean.

5.1.2 LRC Chair appointments will be for a term of 3 years, with extension possible. The letter of appointment includes the date of appointment, length of tenure and indemnity.

5.2 LRC members

5.2.1 Members are appointed by the Deputy Vice-Chancellor (Research and Academic Capability) or delegate on recommendation of the LRC Chair.

5.2.2 Committee members are recruited by direct approach, nomination or by advertisement through an open and transparent selection process.

5.2.3 The letter of appointment includes the date of appointment, length of tenure and indemnity.

5.2.4 Membership of the LR Committee, including member name and school/institute affiliation, may be made publicly available on SCU's web site.

5.2.5 All members are required to complete the University conflict of interest declaration.

5.2.6 Members are appointed for a maximum initial period of 3 years. Subsequent reappointment will occur subject to committee requirements.

5.3 Membership review and lapsed appointments

5.3.1 The Office of the Deputy Vice-Chancellor (Research and Academic Capability) and LRC Chair will continually review membership. New and renewed appointments allow for continuity, development of expertise within the committee, and regular input of fresh ideas and approaches.

5.3.2 Membership lapses if a member:

- Fails to attend LRC review meetings without reasonable excuse or exceptional circumstances
- Fails to attend training or undertake professional development activities related to their role as an LRC member as required by the HREC Chair, LRC Chairs or University
- The appointment of any member of the LRC may be terminated if the HREC Chair/LRC Chairs are of the opinion that it is necessary for the proper and effective functioning of the Panel.
- The Office of the Deputy Vice-Chancellor (Research and Academic Capability) notifies the member of a lapse of membership in writing. Steps are taken to fill the vacancy.

5.3.4 Members seeking to resign or take a leave of absence for an extended period from the LRC are asked to provide written notice to the LRC Chair or delegate so that steps can be taken to fill the vacancy. Furthermore, Heads of School/Institute Deputy Directors should also be advised.

5.3.5 SCU provides indemnity for members of the LRC for liabilities that arise as a result of the member exercising their duties in good faith.

5.4 A LRC coordinator will be appointed by the Office of the Deputy Vice-Chancellor (Research and Academic Capability) to facilitate the administration and processing of LR ethics approval.

6.0 Role of LRC Chairs

6.1 The LRC Chairs are responsible for:

- a) Providing leadership and impartial guidance to the LR Reviewers in relation to the responsible and ethical conduct of research
- b) Fostering appropriate education and training in relation to human research ethics to LR reviewers, researchers and students
- c) Liaising with the LRC coordinator regarding appropriate procedures
- d) Promoting good communication between the reviewers, researchers and the University

- e) Contributing to the development and/or review of SCU policies, procedures and operational guidelines related to human research ethics, including membership of the LRC
- f) Attending to routine and arising matters, including:
 - Reviewing applications and amendments, reports and complaints about the conduct of approved research in a timely manner
 - Moderating reviewer assessment
 - Providing guidance and advice to the SCU research community
 - Promoting awareness of human research ethics principles, processes, and procedures
 - Assisting with recruitment and training of Panel Reviewers
 - Representing SCU in human research ethics forums
 - Supporting the monitoring of compliance and safety in human research

6.2 The LRC Chairs can substitute for one another in their absence or when required due to workload or a conflict of interest.

7.0 Operations

The LRC Terms of Reference are made publicly available on SCU's web site.

7.1 LRC meetings

7.1.1 The LRC meets fortnightly.

7.1.2 Each fortnightly meeting the LRC Chairs, LRC review members, and the Ethics Officer.

7.2 Review of Applications

7.2.1 Applications are submitted through IRMA. The review process is coordinated by the Ethics Office.

7.2.2 The LRC Chairs are responsible for assessing whether each research proposal submitted for review meets the criteria for LR research (National Statement 2.1.6 and the Human Research Ethics Procedure).

7.2.2. Applications are then distributed based on reviewer availability and area of expertise to members of the LRC. Two reviewers will be assigned to each LR application.

7.2.3 To fulfil their responsibilities each member should become familiar with the National Statement and consult other guidelines or legislation relevant to the review of specific research proposals.

7.2.4 Each LRC reviewer will determine whether to recommend:

- a) A proposal be approved
- b) Amendments or clarifications are requested
- c) Resubmission of a new research proposal is required (where extensive amendments are required) or
- d) Referral to HREC on the grounds the proposal does not meet the criteria for LR research.

7.2.5 Where reviewer recommendations about a research proposal differs, the LRC Chairs will be the final decision makers.

7.2.3 The LRC Chairs can meet with reviewers and researchers to discuss issues arising from a review.

7.2.5 The LRC will return approval decisions to researchers within two weeks of receipt of applications for review.

7.3 Declaration of interest

7.3.1. LRC review members must declare any actual, potential or perceived conflict of interest prior to undertaking a review of an LR application.

7.3.2. If there is a conflict of interest the application will be assigned to an alternate reviewer.

7.4 Confidentiality

7.4.1 All LR human research applications remain confidential, unless agreed to by the applicant.

7.5 Records

7.5.1. The LRC will comply with the National Statement requirements for record keeping (5.2.25-5.2.29).

7.5.2. The proceedings of LRC meetings will be documented as per 5.2.28 of the National Statement.

8.0 Complaints

8.1 Action regarding LR rejection

Where the review committee has rejected an application, the investigator has the discretion to submit a new application taking due account of the reviewers' concerns.

8.2 Complaints on the basis of process

If an applicant has a complaint to raise about the conduct of the LRC and considers that the LR Committee has failed to follow due process, they have the discretion to lodge a complaint with the Office of the Deputy Vice-Chancellor (Research and Academic Capability). All complaints will be administered in a timely manner.

8.3 Complaints about the conduct of LR committee members

Complaints about the conduct of an LR committee member are managed by the Ethics Office who informs the LRC Chair of the complaint. Complaints about the conduct of the LRC Chairs are managed by the Deputy Vice-Chancellor (Research and Academic Capability) or delegate.

8.4 Complaints about the conduct of an approved research project

Complaints about the conduct of an approved research project, including allegations of research misconduct, are managed in accordance with SCU's complaint handling procedures.

9.0 Review of Terms of Reference and Termination

9.1 These Terms of Reference will be reviewed every three years.

9.2 Where the LRC is to be adapted, closed, or has ceased to function as per section 3, SCU will amend the Terms of Reference.