SCU Human Research Ethics Low Risk Committee (LRC)
Standard Operating Procedures
(In compliance with Clause 5.1.19 to 5.1.28 of the National Statement on Ethical Conduct in Human Research 2023 (National Statement)

LRC Meeting Procedures and Processes

Frequency of meetings
SCU LRC meets approximately every two weeks.

Attendance at meetings
Attendance of members and visitors is documented. SCU LRC uses the following categories to record attendance:
- Present,
- Apology,
- Apology with comments,
- Absent.

Conduct and structure of meetings and deliberations
LRC Meetings are held in person at the SCU Gold Coast Campus, and also via video conferencing, to facilitate attendance. Time allowance is one (1) hour per meeting and meetings are conducted and mediated by the LRC Chair. Members are to be prepared and to have read all items for discussion and their allocated applications.

The meetings are structured as follows:
- Discussion of low risk research applications: Present members verbally provide their comments and are to submit their written comments using the low risk reporting template to the Research Ethics Officer at the completion of the meeting. If members are unable to attend a meeting but are assigned to review an application, they should submit written comments to the LRC Chair in advance for discussion at the meeting.
- Items for general discussion and other business.

The LRC Chair will allocate applications to each LRC member on the following basis:
a. One primary spokesperson
b. One secondary spokesperson

Only those members assigned will need to review all documents relating to their applications. All members are encouraged to review the Participant Information Sheet for each application.

A 'Traffic Light' system of review and discussion will take place at the meetings, whereby reviewing members should indicate at the meeting if the low risk application requires:
1. Red light: the application presents significant issues for discussion at the meeting, may require full revision and resubmission, or may need to be resubmitted as a high-risk application for full HREC review instead;
2. Amber light: the application requires discussion at the meeting and may require further revision and resubmission;
3. Green light: the application is deemed low risk and meets all criteria for low risk application approval with no discussion needed.

Applications will be reviewed and discussed 'live' at each LRC meeting as follows:
1. Primary spokespeople are expected to lead discussion on each application they are assigned by:
   a. Reviewing the assigned applications in advance of each respective meeting and completing the low risk review template
   b. Assignment of the appropriate 'Traffic Light' for application discussion at the meeting

    c.   Opening the application documents on IRMA at the meeting for other LRC member's consideration

    d.   Lead discussion of their comments on applications, as per the Low Risk review template and the National Statement principles

    e.   Finalising comments on the review template following discussion of the application

    f.   Entering their final comments from the template in the first review box on the 'Committee outcome' tab of the application on IRMA, and selecting 'yes' to complete the review process

    g.   Where there is a second reviewer, the primary spokesperson is to assign the second reviewer to the application on IRMA, to enter their comments on the application in accordance with the Low Risk review template.

Discussions are documented and the views of all members are considered.

Preparation of agendas and minutes and timely distribution of papers before meetings

Agendas are prepared by the Research Ethics Officer. Agendas are sent to members at least five days before the meeting, to allow sufficient time for consideration of agenda items. Records of meetings are sent to the Chair for approval.

Attendance, as observers, of people other than members or researchers at meetings (see paragraph 5.2.20 of the National Statement)

Researchers can be invited to a meeting for the opportunity to participate in the discussion about the proposal and respond to questions about the application. LRC can also invite specialists, for consideration of certain applications or for training purposes. Deputy Vice Chancellor Research and Academic Capability (DVCRAC) representatives may also participate as observers. The above mentioned meeting attendees, or any attendees other than LRC Members, are documented as observers / visitors. Visitors withdraw from the meeting for confidential matters.

LRC Approval and Monitoring Processes

Presentation of applications for ethics review and timely consideration and review of applications

SCU LRC requires ethics approval of all Low Risk research involving humans. Determination of the level of risk is based on Chapter 2.1 of the National Statement. Participant considerations are guided by Section 4. Researchers are required to submit their applications via SCU's Research Management System (IRMA). IRMA captures all the reviewed documentation and review outcomes.

Low risk applications are considered within approximately two weeks from receipt of application in IRMA. If applications are deemed higher risk, responses will be sent to researchers within one week following a low risk meeting, and notified to submit a full application to the Human Research Ethics Committee for high-risk review.

Low risk applications will specifically be reviewed in accordance with the following principles and elements of the National Statement:

1.   Research merit and integrity (National Statement 1.1 -1.3)
2.   Recruitment and Consent (National Statement Element 2 and 3)
3.   Respect for Privacy and Confidentiality (National Statement 1.11; 2.26)
4.   Risk and Benefit (National Statement 2.1)
5.   Reuse of data and dissemination (National Statement Elements 4-6)

All supporting documentation accompanying Low Risk applications will also be considered in accordance with these principles.

Managing conflicts of interest (see NS chapter 5.4)

Management processes for conflicts of interest involving the institution:

- LRC informs SCU about any research conducted that poses a conflict of interest to the institution.

Management processes for declaration of interest involving the researcher:

- SCU researchers are bound by the Conflict of Interest policy in the SCU Code of Conduct.
- LRC requires researchers to enact measures as outlined in 5.4.3 to manage conflicts of interest.

Management processes for conflicts of interest involving LRC, their members or advisors:

- Low Risk review will be deferred to the next authorised Low Risk reviewer.
- Low risk application review process:
  - The person with the conflict of interest will be asked by LRC to retire from the meeting until invited to return.
  - The Committee decides if the person with the conflict of interest can be present in the room during the discussion. Yes / No response documented.
  - The Committee decides if the person with the conflict of interest can participate in the discussion. Yes / No response documented.

Communicating with researchers, including face-to-face, by telephone and in writing (including email) (see paragraphs 5.2.14 to 5.2.16)

- SCU encourages informal communication. The LRC Chair is readily available to researchers via email and happy to meet face-to-face (including by Zoom). All contact details of the Ethics Office and the LRC Chair are made available via the SCU website. Researchers can be invited to attend LRC meetings.

Methods of decision making

Decisions following review are made as follows:

- Low Risk Applications: Recommendation by the Primary spokesperson to be ratified by the Secondary spokesperson and the LRC Chair. Final decisions are to be made by majority vote of the full committee. The LRC Chair has the authorisation to finalise decisions on behalf of the committee.
  - The committee may:
    - authorise the Chair to finalise decision on receipt of clarification or extra information where the committee has requested such; or
    - require the application to be reconsidered at a following meeting, to require a majority vote for approval.
- Flying Minute: The LRC Chair may determine that urgent matters requiring the Committee's consideration between meetings may be conducted by flying minute. Flying minutes require a simple majority.

Prompt notification of decisions

For all review processes the SCU LRC has the following timeframes to communicate decisions on applications.

- For Low Risk application, two weeks from the application submission closing date for the respective LRC meeting.

Record keeping (see paragraphs 5.2.25 to 5.2.29)

All records are kept on a cloud server, which is backed up daily, in accordance with paragraphs 5.2.25 – 5.2.29. Access to the records data is restricted to members who have explicit access to the folder or IRMA.
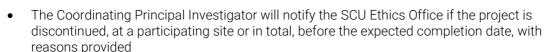
The Research Ethics Officer is required to:

- enter all data as required under paragraph 5.2.27 in IRMA.
- all official letters of advice from LRC, original applications and attachments to the applications, such as information sheet and consent forms

Monitoring of approved research (see paragraphs 5.5.1 to 5.5.6)

SCU requires the following monitoring activities to be undertaken by researchers:

- The Coordinating Principal Investigator will report to the SCU Ethics Office annually in the specified format and notify the Ethics Office when the project is completed
- The Coordinating Principal Investigator will immediately notify the SCU Ethics Office, via IRMA, if any change in protocol is needed, by submitting a Change of Protocol application for approval.

- The Coordinating Principal Investigator will notify the SCU Ethics Office if the project is discontinued, at a participating site or in total, before the expected completion date, with reasons provided
- The Coordinating Principal Investigator will notify the SCU Ethics Office of any need to extend the duration of the project past the approval period listed above and will submit any associated required documentation
- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethics approval of the project on the Adverse Events form.

These are communicated as standard conditions of approval on all official letters from LRC, via training and on the ethics website. LRC may require researchers to submit additional reports depending on the degree of risk of their project. This will be communicated as a special condition of approval.

Ethics Management have procedures in place to track annual report due dates and remind researchers when these dates are coming up for their research.

Receiving and handling of complaints (see paragraph 5.6)
Refer to Ethics website for complaints procedures.

Advising the institution/s of decisions to withdraw ethical approval of a research project (see paragraphs 5.5.7 to 5.5.12)
Where SCU LRC, the Chair of LRC or the institution have reason to believe that continuation of a research project will compromise participants' welfare, the researcher is requested to cease all research until protection has been established or the project amended to guarantee participant protection.

Fees, if any, to be charged
No fees are charged for any LRC services.

Appropriate confidentiality of the content of applications and the deliberations of review bodies
All review processes and meetings are confidential. Applications and records of meetings are kept on a protected folder and database. LRC Members are obliged to adhere to the SCU Code of Conduct, which clearly states that they must not disclose, disseminate or make use of confidential information relating to the University's affairs that they gain access to during their engagement on LRC. Members sign an offer letter acknowledging that they have read and understood both the SCU Code of Conduct, along with Confidentiality Agreements as required.

LRC Reporting

Reporting on its activities to the institution and reporting and handling of adverse events
The Research Ethics Officer provides the DVCRAC with the NHMRC annual report for review and approval. The LRC Chair regularly meets with the DVCRAC to discuss any ethics issues. Reports on human ethics submissions are made available to Faculties on request.

Adverse Incidents
An adverse incident may be a harmful, unpleasant, or undesirable response, reaction, or outcome experienced by a research participant or researcher. Such incidents may include unanticipated harm to participants – including physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage – or harm to the researchers and/or the University or their reputation. Researchers must report serious incidents within 72-hours to the Ethics Office.

Other adverse incidents that might have an impact on the continued ethical acceptability of the project must be reported to the Ethics Office as soon as possible. This includes instances of privacy breaches, loss of data, damage to property and other similar occurrences.