Southern Cross University Human Research Ethics Committee (HREC) Procedures In compliance with Clause 5.1.37 of the Statement

HREC Meeting Procedures and Processes

(a) Frequency of meetings;
Southern Cross University HREC meets eight times per year, approximately every six weeks.

(b) Attendance at meetings;
Attendance of members and visitors is recorded in the minutes to each meeting. Southern Cross University HREC uses the following categories to record attendance: Present, Apology, Apology with comment, Absent. Members are encouraged to attend or communicate their views before the meeting so to attain a quorum decision on agenda items. The Chair formally presents submitted comments to the meeting.

(c) Conduct and structure of meetings and deliberations;
HREC Meetings are held via video conferencing, so to facilitate attendance. Time allowance is three hours per meeting and meetings are conducted and mediated by the HREC Chair or Deputy Chair. Members are to be prepared and to have read all items for discussion. The meetings are structured as follows:

- Ratification of previous minutes and approval of all decisions made therein
- Discussion of moderate to high risk research applications
- Ratification of negligible to low risk applications, Minimisation of Duplication Applications and Changes of Protocol
- Noting and ratification of Annual – and Completion Reports
- Items for general discussion

HREC has established an expedited approval process by which negligible to low risk applications, minimisations, changes of protocol and reports are approved by the expedited committee and the Chair. Discussions are recorded in the minutes and the views of all members are considered.

(d) Preparation of agendas and minutes; and (e) timely distribution of papers before meetings;
Agendas and minutes are prepared by the secretary to HREC. Agendas are sent to members 10 days before the meeting, to allow sufficient time for consideration of agenda items. Minutes are sent first to the Chair for perusal and then to members within one week after the meeting, with ratification thereof at the following HREC meeting.

(r) Attendance, as observers, of people other than members or researchers (see paragraph 5.2.18) at meetings;
Researchers are sometimes invited to a meeting for the opportunity to participate in the discussion about the proposal and defend the application. HREC also sometimes invites specialists, for consideration of certain applications or training purposes. DVCR representatives also sometimes participate as observers. The abovementioned meeting attendees, or any attendees other than HREC Members, are recorded in the minutes as observers/visitors. Visitors withdraw from the meeting form confidential matters.
HREC Approval and Monitoring Processes

(f) Presentation of applications for ethical review; (g) timely consideration and review of applications;

Southern Cross University HREC requires the ethical approval of all research involving humans and has established two main approval processes:

- Expedited review for all research involving negligible to low risk
- Full HREC review for all research involving moderate to high risk research or involving participation of certain groups of people.

Determination of the level of risk is based on Chapter 2.1 of the Statement. Participant considerations are guided by Section 4.

Researchers are required to submit digital files to the ethics office on ethics.lismore@scu.edu.au. The Ethics Office records all communication and details of the project and determines the review process.

Expedited applications are considered by the Chair and expedited committee on behalf of HREC within 10 working days from receipt of application.

Higher risk applications are presented at a full meeting and responses sent to researchers within 10 working days of the meeting.

(h) Managing conflicts of interest (CoI) (see paragraphs 5.4.1 to 5.4.6);

(a) Management processes for conflicts of interest involving the institution:

- Application forms include a questions about institutional interest in research
- HREC informs Southern Cross University about any research conducted that pose a conflict of interest on the questions about measures to manage them

(b) Management processes for declaration of interest involving the researcher:

- Application forms include a question about declarations of interest involving the researcher as well as questions about measures to manage them
- HREC requires researchers to adapt measures as outlined in 5.4.3 to manage Conflicts of Interest

(c ) Management processes for conflicts of interest involving HREC, their members or advisors:

- Expedited review will be deferred to the next authorised expedited approver
- NEAF review process:
  1. Person with Col will be asked by HREC to retire from the meeting until invited to return
  2. Committee decides if person with Col can be present in the room during the discussion. Yes / No response recorded in the minutes
  3. Committee decides if person with Col can participate in the discussion. Yes / No response recorded in the minutes

(i) Communicating with researchers, including face to face, by telephone and in writing (including email) (see paragraphs 5.2.13 to 5.2.15);

- Southern Cross University encourages informal communication. The Chair is readily available to researchers via email and happy to meet face to face. All contact details of the Ethics Office and the Chair are made available via the Southern Cross University website. All email communication is saved under the protocol file. Researchers are invited to attend HREC meetings.
- HREC endeavors to make available an expert advisory panel for researchers to discuss specialised projects
(k) Methods of decision making;
Decisions following review are made as follows:
1. Expedited Application: The Chair finalises the decision on behalf of the committee, ratified at the next committee meeting.
2. Full Application: The decision is made by majority vote of full committee.
   a. The committee may authorise the chair to finalise decision on receipt of clarification or extra information where the committee has requested such or
   b. Require the application to be reconsidered at a following meeting, to require a majority vote for approval.

(l) Prompt notification of decisions;
For all review processes the Southern Cross University HREC has the following time frames to communicate decisions on applications.
- For expedited, 10 working days from receipt of application at the ethics office.
- For higher risk, 10 working days from the HREC meeting at which the application was reviewed.

(m) Record keeping (see paragraphs 5.2.23 to 5.2.27);
All records are kept on a cloud server, which is backed up daily, in accordance with paragraphs 5.2.23 – 5.2.27. Access to the data is restricted to members who have explicit access to the folder.
- entering all data as required under 5.2.24 in an ACCESS database
- saving all correspondence in email format in a separate folder
- saving all official letters of advice from HREC, original applications and attachments to the applications, such as information sheet and consent forms

(n) Monitoring of approved research (see paragraphs 5.5.1 to 5.5.5);
Southern Cross University requires the following monitoring activities to be undertaken by researchers:
1. The Coordinating Principal Investigator will report to the Southern Cross University HREC annually in the specified format and notify HREC when the project is completed.
2. The Coordinating Principal Investigator will immediately notify the Southern Cross University HREC, on the appropriate form, of any change in protocol.
3. The Coordinating Principal Investigator will notify the Southern Cross University HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
4. The Coordinating Principal Investigator will notify the Southern Cross University HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
5. The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project on the Adverse Events form.

These are communicated as standard conditions of approval on all official letters from HREC, via training as well as on the ethics website. HREC may require researchers to submit additional reports depending on the degree of risk. 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.

(p) Receiving and handling of complaints (see paragraphs 5.6.1 to 5.6.7);
Please refer to attachment 1.
(q) Advising the institution/s of decisions to withdraw ethical approval of a research project (see paragraphs 5.5.7 to 5.5.9);

Where Southern Cross University HREC, the Chair of HREC 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.

(s) Fees, if any, to be charged; and

No fees are charged for any HREC services.

(t) Appropriate confidentiality of the content of applications and the deliberations of review bodies.

All review processes and meetings are confidential. Applications and Meeting Minutes are kept on a protected folder and database. HREC Members are obliged to adhere to the Southern Cross University Code of Conduct and Volunteer Policy, which clearly state 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 HREC. Members sign an induction form acknowledging that they have read and understood both the Southern Cross University Code of Conduct and Volunteer Policy.

HREC Reporting

(j) Reporting on its activities to the institution and (o) reporting and handling of adverse events;

Ethics Management provide reports to the Head of Work Unit which are presented to the DVC(R), usually every two months, on all applications that were considered at a meeting, complaints or adverse events notifications received as well as any decisions made during the meeting. This report also includes current projects of the Ethics Manager in regards to training and support for researchers as well as compliance reviews.

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 advantage – or harm to the researchers and/or the University or their reputation. Researchers must report serious incidents within 72 hours to the Human Research Ethics Committee (HREC).

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

Adverse Incidents in Clinical Trials

The Human Research Ethics Committee (HREC) should be notified of any information or event that has an impact on the continued ethical acceptability of the trial, and any “serious” adverse event whether it is causally related to the study intervention, and whether it is expected or not. These events should be reported within 72 hours of the event occurring.
Appendix 1

HREC Complaints Procedure and Policy according to the “National Statement” and the “Australian Code for the Responsible Conduct of Research”

Input

Direct 3rd Party

Complaint related to either:
- Ethical conduct
- HREC process
- HREC decision
- other

Refer back or onto other entity

Non HREC related

Complaint Received, documented in casefile and categorized

HREC related

Appeal against HREC (based on NS)

HREC Decision

Resolve between HREC Chair and Complainant

Unresolved

Resolve between HREC and Complainant

Unresolved

HREC Administrator to develop Memo and recommendations to DVCR

Seek recommendation outside HREC

Unresolved

Investigate (ID error in initial decision) and recommend action to resolve

Resolved

Seek recommendation Ex-Institutionally

Unresolved

Investigate (ID error in initial decision) and recommend action to resolve

Resolved

Document and Action:
- Casefile
- HREC Agenda
- Inform DVCR and VC as required
- Communicate to 3rd party as required
- Communicate to complainant

Ethical Research Misconduct (based on Code)

Discreet informal Investigation

No case or resolved

Formal Inquiry

Resolved

Action to remedy the situation

Resolved

Imposition of a sanction / penalty

Advice to expert groups and public statements as required