



Charles Sturt University Human Research Ethics Committee Procedures

- ❖ This document contains two sections: one detailing CSU specific procedures, and the other detailing procedures required by clause 5.1.37 of the *National Statement on Ethical Conduct in Human Research* (the *National Statement*)
- ❖ Numbers in square brackets refer to relevant sections of the *National Statement*

CSU specific procedures

HREC Executive

- The HREC Executive will be made up of a Presiding Officer and two Deputy Presiding Officers, appointed by the DVC-RE for a period of three years.
- The Deputy Presiding Officers will be assigned to different Panels, while the Presiding Officer will sit on both Panels.
- The Executive will consider requests for the extension and/or variation of approved projects review, and requests for approval of projects approved by another HREC. Review of these requests will be based on the standards and values of the *National Statement*.
- The Executive may decide to review projects that are not greater than low risk between scheduled meetings when determined necessary, e.g. by deadlines or funding agency requirements.
- All decisions made by the Executive about existing or newly-considered projects will be noted on the next available agenda for ratification by the Committee.
- Both Deputy Presiding Officers can exercise any of the functions of the Presiding Officer when the latter is absent from the University.

Appointment of members

- The Research Integrity, Ethics and Compliance Unit will have responsibility for sourcing members for the HREC, including alternate members, with a view to meeting the requirements of the *National Statement*.
 - The details of possible members shall be forwarded to the Chair for a determination based on the prospective member's experience and qualifications, and the needs of the Committee in relation to its *National Statement* obligations.
- The Presiding Officer will forward recommendations about new members to the DVC (RE), who will make formal appointments to the Committee.
- Individual members will be allocated to a Panel by the HREC Executive, taking into account *National Statement* requirements about relative numbers of men and women, and internal and external members, and any other criteria in the Committee's Terms of Reference. Members' preferences in relation to Panel meeting dates will be sought to inform decisions about Panel allocation.
- If deemed necessary to ensure compliance with the *National Statement* or other criteria in the Committee's Terms of Reference, the Presiding Officer may consult with a specific member about ongoing or temporary transfer to the other Panel.

- The Presiding Officer is responsible for identifying a relevant induction program for new members, and for ensuring that each member, including alternate members, completes the program before they begin to review applications.
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Consistency between Panels

- The Chair will provide a verbal report to each Panel meeting.
 - The Presiding Officer will be responsible for ensuring that the same information is shared with each Panel so that consistency of practice and information between the Panels is maintained.
 - The agenda papers and minutes of each Panel will be available to members of the other Panel in a manner to be determined by the Manager, Research Integrity, Ethics and Compliance Unit in consultation with the Presiding Officer. Panel members will be advised they should only consult the minutes and agenda of the other Panel where they can state a legitimate reason for doing so (e.g. for learning purposes, because they will be attending a meeting of the other Panel).
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Minutes and Letters to Researchers

- Feedback to researchers will clearly align with the values and any other relevant sections of the *National Statement* and with established University documentation requirements.
 - Each item of feedback to researchers will provide detail of the Committee's reasoning, and a clear statement of what the researchers are being asked to do or consider.
 - Researchers will not be asked to provide amended or additional documents simply to correct the misplacement of information in their initial application.
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National Statement requirements

The Committee's Terms of Reference will be publicly listed in the University's policy library. <https://policy.csu.edu.au/document/view-current.php?id=130>, as per 5.1.27 of the *National Statement*

5.1.37 An institution that establishes an HREC should ensure that the HREC establishes, implements and documents working procedures to promote good ethical review, including procedures for:

- (a) *Frequency of meetings;*
- Meetings of the Committee will be held fortnightly, except during January, with each Panel meeting approximately fortnightly.
 - Meetings will usually be held from 9am – 1.30pm.
 - The Research Integrity, Ethics and Compliance Unit will be responsible for posting the schedule of meeting dates and agenda closing dates to the HREC website by the beginning of each academic year.
 - In exceptional circumstances, the schedule of Panel meetings may be altered by the Presiding Officer in consultation with the Manager, Research Integrity, Ethics and Compliance Unit. Any alterations to the meeting schedule should:
 - Minimise disruption to applicants, and
 - Be disseminated without delay to the University community.
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- (b) *Attendance at meetings;*
- Meetings will be held via appropriate means, for example video-conference, tele-conference, face to face.
 - Members unable to attend a meeting may submit comments in writing to the Presiding Officer, who will ensure those comments are put forward at the meeting.
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- (c) *Conduct and structure of meetings and deliberations;*

Chairing of meetings:

- Meetings will be chaired by the Presiding.
- Where the Presiding Officer is absent from a meeting, the respective Deputy Presiding Officer will chair the meeting.
- If neither the Presiding Officer nor the respective Deputy Presiding Officer can attend a meeting, an experienced Panel member will be appointed Chair for that meeting by the Presiding Officer.

Decision making:

- Each Panel will review and manage to completion the applications on the agendas provided to that Panel.
- Decisions about whether a research proposal meets the requirements of the *National Statement* must be informed by an exchange of opinions from each of those who constitute the minimum membership. This exchange should, ideally, take place at a meeting with all those members present [5.2.29].
- All documents and other material that form part of an application should be reviewed by the Panel to which an application has been assigned [5.2.23].
 - This includes, but is not limited to: recruitment material (advertisements, letters of invitation, information sheets and consent forms); and interview schedules, questionnaires, and other research instruments.
- Where there is less than full attendance of the minimum membership at a meeting, the Presiding Officer (or other person chairing the meeting) should be satisfied, before a decision is reached, that the views of

those absent who belong to the minimum membership have been received and considered [5.2.30].

- Each Panel of the Committee should endeavour to reach decisions by general agreement. This need not involve unanimity [5.2.31].

(d) *Preparation of agendas and minutes;*

- Agendas and minutes will be prepared by the Governance Officer and reviewed by the Presiding Officer prior to distribution to members.
- Agendas and minutes should be consistently formatted, as per University requirements.
- Minutes of each meeting will be drafted by the Governance Officer as soon as possible after each meeting, and reviewed and approved by the Presiding Officer.
- To ensure timely responses to researchers, letters containing feedback on applications will be extracted from the approved Minutes and emailed by the Governance Officer as soon as possible after approval of the Minutes. .
- Minutes will be confirmed at the next scheduled meeting of the relevant Panel.

(e) *Timely distribution of papers before meetings;*

- The agenda for each meeting will close two weeks prior to the date of the meeting.
- Papers for scheduled meetings will be distributed to the assigned Panel members as soon as possible after the agenda closing date, and no later than 5 days before the meeting.
- Late papers may be circulated to the respective Panel members at the discretion of the Presiding Officer (or other person chairing the meeting) and in consultation with the Governance Officer.

(f) *Presentation of applications for ethical review;*

- The relevant Governance Officer will check all submissions from researchers, and request any missing documents or other items.
 - Except in extenuating circumstances, incomplete applications will not be included on an agenda.
- All applications received will be issued a Project Identifier.
- All elements of an application shall be included with the respective agenda in a clearly labelled and numbered way.

(g) *Timely consideration and review of applications;*

- Applications, and any documents to be considered by a Panel will be allocated to an agenda based on their submission date and the next agenda closing date.
 - The Presiding Officer may vary this procedure (without disadvantage to applicants) to balance workload between Panels.
- Letters to researchers should be sent no more than 10 days after the meeting at which they were considered.
- All letters should use the template developed by the HREC to indicate correspondence between Committee feedback and the elements of the National Statement.
- If researchers request urgent review of an application that involves greater than low risk research outside the scheduled meeting times, such review can be undertaken at the Presiding Officer's discretion.
 - a. The Presiding Officer will determine which Panel should review the application (taking into account the respective meeting dates of each Panel and members' likely ability to undertake the additional review) or, if necessary, convene a fully constituted panel from across the Committee membership.
 - b. If possible, a meeting via video- and tele-conference should be convened; otherwise, the application can be considered via

email exchanges, with the Governance Officer and Presiding Officer collating responses.

- Decisions made outside regular meetings must be recorded on the relevant Panel's next agenda, or on the next available agenda if a fully constituted panel from across the Committee membership was convened.
- Applications from student researchers should not be reviewed until signed by the supervisor/s.
- All other applications may be reviewed even if not all signatures from co-researchers have not been obtained – but final approval cannot be given until all signatures have been received.
- Final approval of an application cannot be given until evidence of evaluation of academic merit has been reviewed.
- Responses to reviewed applications must take one of the following three forms:
 - a. **Approved** [no further clarification or information required from the researcher/s];
 - b. **Approved subject to satisfactory clarification of a number of issues in line with the *National Statement***
 - i. In this case the HREC should determine how many members should review the clarifications [usually 1 – 3, depending on the extent and nature of the clarifications, and the degree of risk posed by the research];
 - ii. Clarifications should be reviewed between meetings and approval given once all reviewing members are satisfied with the responses.
 - iii. Where researchers raise new issues, i.e. issues not considered at the respective Committee meeting, members should cease review of the material from the researchers and refer the application back to the next meeting of the respective Panel (via the Presiding Officer and Governance Officer).
 - c. **Resubmit** [revision/review required by the researcher/s exceeds clarification of a number of issues – rather, the project is under-developed overall].
 - i. A re-submitted application must be reviewed at a full Panel meeting, but not necessarily by the Panel that originally considered the application.
 - d. **Declined** [the project is ethically unacceptable in ways that cannot be addressed by further development or clarification].

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

- Any member who has a conflict of interest in relation to an application should inform the Presiding Officer (or other person chairing the relevant meeting) at the first available opportunity.
- Members who have a conflict of interest should absent themselves from that part of a meeting where the relevant application is discussed, and should not be involved in any subsequent deliberations related to the application. If the expertise of the relevant member is necessary for the deliberations this should be provided in writing.
- Any expert adviser (not a HREC member) who has a conflict of interest related to the application they are advising on may be asked to provide written advice only.

- (i) *Communicating with researchers, including face to face, by telephone and in writing (including email) (see paragraphs 5.2.13 to 5.2.15);*
- Most communication with researchers will be via the Governance Officer, when applications and other reports are submitted, or letters sent from the reviewing Panel.
 - Where necessary, a meeting may be scheduled with a researcher/s to assist in resolving on-going or complex issues.
 - This may occur by way of the Committee nominating relevant members to contact, or be contacted by, the researcher [5.2.14], or by way of the Presiding Officer identifying relevant members if the need for such a meeting becomes apparent in between scheduled Committee meetings.
 - Good ethical review requires ready accessibility of Committee members to researchers and open communication between members and researchers [5.2.13]. Therefore, the Presiding Officer and Governance Officer may delegate researcher inquiries to members as necessary between meetings.
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- (j) *Reporting on its activities to the institution;*
- The Committee shall provide quarterly reports to the Finance, Audit and Risk Committee (CSU) via the Presiding Officer.
 - Other reporting may be required on an occasional basis.
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- (k) *Methods of decision making;*
- The Presiding Officer has the executive power to make decisions between meetings, without consulting members or after consultation with a limited number of members.
 - These decisions will not typically involve review of full ethics applications.
- Also see (c) above
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- (l) *Prompt notification of decisions;*
- Covered in (g) above
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- (m) *Record keeping (see paragraphs 5.2.23 to 5.2.27);*
- Research Master and Unirecords information systems will be used to maintain a record of all research proposals received and reviewed, including at least:
 - a) Identification of the reviewing Panel;
 - b) Name/s of the institution/s to which the research approval is provided;
 - c) Project identification number/s;
 - d) Name/s of principal researcher/s;
 - e) Title of the project;
 - f) Correspondence between the review body and the researcher about the review;
 - g) Acceptance or rejection of any changes to the proposal;
 - h) Proposed date of completion of the proposal;
 - i) Formal advice of final ethical approval or non-approval, with date;
 - j) Terms and conditions, if any, of approval of any proposal;
 - k) Duration of the approval;
 - l) Name of any other review body whose opinion was considered;
 - m) Mechanisms to be used to monitor the conduct of the research;
 - n) Relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information [5.2.24];

- o) Whether the project constitutes a clinical trial; and
- p) Any other information required on a regular basis for meeting the Committee's reporting responsibilities.
- The Committee should retain on file a copy of each research proposal and application for ethical approval, including all documents and other material used in recruiting potential research participants (such as advertisements and letters of invitation), information sheets and consent forms, interview schedules, questionnaires, and other research instruments, and any other relevant correspondence, *in the form in which they were approved* [5.2.25].
- The Committee uses Unirecords to record decisions about approval, amendment or rejection of proposals in written or electronic form, with reasons for those decisions, linking those reasons to the *National Statement* [5.2.26.]
- To avoid duplication of ethical review, the outcome of another fully constituted HREC's review of a proposal may be accepted and recorded in Unirecords, without additional review.
 - Recording should not take place until the HREC Executive has checked the documentation for matters such as correct identification of the University.
 - Recording should include notification on the agenda of the next available Committee agenda.

(n) *Monitoring of approved research (see paragraphs 5.5.1 to 5.5.5);*

- An Annual Report shall be requested for all approved research projects. In some instances reports may be required at shorter intervals, at the discretion of the reviewing Panel and based on the nature of the research proposal.
 - Annual reports should be tabled on the agenda of the reviewing Panel.
- Where a project is approved for a period exceeding 12 months, that approval will be contingent on each Annual Report assuring the reviewing Panel that the research is proceeding as approved.
- Researchers will also be required to complete a Final Report on their project once it is concluded.
 - This Report should be included on the agenda of the reviewing Panel and made available to members of the other Panel.
- Research Master systems will issue periodic reminders to researchers of when their reporting requirements fall due.

(o) *Reporting and handling of adverse events; (see paragraphs 5.1.37(o) and 5.5.3)*

- Researchers must report serious adverse events to the HREC as soon as possible.
Adverse events are unexpected events that impact on the research process or have consequences for participants, and may include protocol deviations.
- A number of reporting forms are managed by the HREC for this purpose, including requests for variations and requests for extensions and an adverse event report form.
- The Presiding Officer will assess each report and act according to the severity and impact of the adverse event. In most cases the event will be handled as reviewed and approved variations and extensions, but in cases of potential harm the researchers may be required to cease research while the event is investigated.

(p) *Receiving and handling of*

- On receiving a complaint, either from researchers about the consideration of their research protocol by the HREC or from

complaints (see paragraphs 5.6.1 to 5.6.7);

participants or potential participants about the conduct of an approved research project, the Complaints Officer (i.e. the Governance Officer) will:

- Contact the researcher/s, including supervisor/s where relevant, and advise they should cease all work on the research project until advised otherwise by the HREC.
- Advise the Presiding Officer of the complaint.
- On being advised of a complaint, the Presiding Officer will contact the researcher/s, including supervisor/s where relevant, to seek an explanation of the events which have given rise to the complaint.
- On receipt of this explanation, the Presiding Officer may:
 - Determine that no further action is required (in which case, the complainant and researcher/s will be notified in writing of this decision); or
 - Determine that the matter requires further investigation or action, including (but not limited to):
 - Suspend HREC approval while the matter is investigated;
 - Request evidence that the researcher is conducting the research in keeping with the terms of the HREC approval;
 - Place further conditions on the continued conduct of the research;
 - Require that all or some data be brought to the Complaints Officer for secure storage;
 - Approach the Deputy Vice-Chancellor (Research and Engagement) to inform him/her of the complaint;
 - Recommend further investigation of the complaint by the Deputy Vice-Chancellor (Research and Engagement);
 - After full investigation, revoke approval for the research and require that all data that has been collected be brought to the Complaints Officer for secure storage.
 - Where the nature of the complaint requires further investigation, researchers will receive written information about the process being undertaken, and the complainant will be assured in writing that relevant processes re continuing.
- Researchers who believe that a complaint is unwarranted or that the handling of the complaint is unfair are entitled to lodge a formal complaint or appeal to the Deputy Vice-Chancellor (Research and Engagement).
- Where ethical approval for a research project is withdrawn:
 - the researcher, the institution/s and, where possible, the participants should be informed of the withdrawal;
 - the institution must ensure that the researcher promptly suspends the research and makes arrangements to meet the needs of participants; and
 - the research may not be resumed unless either
 - the researcher subsequently establishes that continuance will not compromise participants' welfare;or

	<ul style="list-style-type: none"> ▪ the research is modified to provide sufficient protection for participants, the modification is ethically reviewed, and the modified research is approved [5.5.8]. • The Presiding Officer may seek intervention from the management of the institution to ensure research is in fact suspended.
(q) <i>Advising the institution/s of decisions to withdraw ethical approval of a research project (see paragraphs 5.5.7 to 5.5.9);</i>	Covered above in (p)
(r) <i>Attendance, as observers, of people other than members or researchers (see paragraph 5.2.18) at meetings;</i>	<ul style="list-style-type: none"> • The Committee may invite researcher/s, and researchers may request, to be present for discussion of their proposed research [5.2.18]. • The researcher/s will be asked to leave the meeting before the Committee begins deliberation on their application. • A review body may seek advice from experts to help in considering a research proposal. Such experts must be advised that they are bound by the same confidentiality requirements as the Committee. Any conflicts of interest they may have should be disclosed and managed [5.2.19] • Communication between a research sponsor and the Committee should be avoided where it may, or may be perceived to, influence the ethical review and approval of the project [5.2.20]. • Any attendees at all or part of a meeting will be asked to maintain confidentiality of the matters they observe.
(s) <i>Fees, if any, to be charged; and</i>	<ul style="list-style-type: none"> • The charging of fees for review of projects external to the University will be considered on a case by case basis. External projects will be accepted for review on the approval of the Deputy Vice Chancellor (Research and Engagement) and an administrative fee of \$200 will be applied).
(t) <i>Appropriate confidentiality of the content of applications and the deliberations of review bodies.</i>	<ul style="list-style-type: none"> • All papers tabled at a Committee meeting and all discussions taking place at that meeting are confidential to meeting attendees. • Specific papers considered during a meeting and records of specific meeting discussions may be shared with authorised officers of the University who can demonstrate a need to know the relevant information for the performance of their duties.