

'Human Research Ethics Committee' - Membership and Terms of Reference

Section 1 - Establishment

Background

- (1) The Human Research Ethics Committee was established in 1991, under the provisions in the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research.
- (2) The Human Research Ethics Committee (the Committee) reports to the Deputy Vice-Chancellor (Research) and, through the Deputy Vice-Chancellor (Research) to the Finance, Audit and Risk Committee of the University Council.
- (3) As of January 2018, the Committee consists of two panels, each of which is fully constituted under the membership requirements of the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research. Each panel has additional membership categories as deemed relevant to the Committee's role in the University.

Purpose

(4) The Human Research Ethics Committee reviews research proposals involving human participants to ensure that they are ethically acceptable and follow relevant standards and guidelines.

Section 2 - Glossary

- (5) For the purposes of this document:
 - a. Chair, Panel 1 means the person leading and presiding at a meeting of Panel 1;
 - b. Chair, Panel 2 means the person leading and presiding at a meeting of Panel 2;
 - c. Committee means the Human Research Ethics Committee;
 - d. Deputy Presiding Officer means a Deputy Presiding Officer of the Committee;
 - e. External member means a member appointed to the Committee because of their specific expertise or as a representative of a particular group or category of membership, who is not:
 - i. an employee of the University or a controlled entity of the University;
 - ii. a member of the University Council or a committee of the University Council;
 - iii. a current student.
 - f. Member/s means member/s of the Human Research Ethics Committee (where necessary, members of a Panel are specifically identified as such);
 - g. National Statement means the National Statement on Ethical Conduct in Human Research produced by the National Health and Medical Research Council (NHMRC);
 - h. Panel means a panel of members of the Human Research Ethics Committee who meet to review, discuss and approve proposals, applications and other relevant Committee business. Each panel is fully constituted in terms of these Membership and Terms of Reference;

- i. Presiding Officer means the Presiding Officer of the Committee;
- j. Reviewing Panel means the Panel which considered an application; and
- k. the University means Charles Sturt University.

Section 3 - Membership

- (6) As per the National Statement on Ethical Conduct in Human Research, members are appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation or group.
- (7) The Committee has one Presiding Officer and up to two Deputy Presiding Officers, each of whom are nominated by the Deputy Vice-Chancellor (Research).
- (8) Each Panel is ordinarily chaired by a Deputy Presiding Officer, with the Presiding Officer having oversight of the entire Committee. The Presiding Officer may either chair a Panel meeting in the absence of a Deputy Presiding Officer, or may nominate an acting Chair for the required period of time.
- (9) The Committee membership is determined by:
 - a. categories of membership required by the National Statement on Ethical Conduct in Human Research (identified below with an asterisk). This is the minimum membership of the Committee; and
 - b. categories of membership identified as desirable to fulfill the Committee's role within the University, noting the following:
 - i. as these categories have not been deemed necessary by the National Statement on Ethical Conduct in Human Research, a vacancy in all or any of them will not compromise the Committee's compliance with National Health and Medical Research Council membership requirements as per the National Statement on Ethical Conduct in Human Research.
 - ii. where filled, these categories must be taken into account in ensuring the Committee's compliance with the National Statement on Ethical Conduct in Human Research.
- (10) Each Panel of the Committee comprises of the following minimum membership, as per clause 9 (a):
 - a. a Chair as per clause 8 above, or an Acting Chair, to be determined by the Presiding Officer, for leading Panel meetings in the absence of the Presiding Officer or Deputy Presiding Officer;
 - b. a Lawyer, where possible one who is not engaged to advise the institution*;
 - c. a Layman who has no affiliation with the institution and does not currently engage in medical, scientific, legal or academic work*;
 - d. a Laywoman who has no affiliation with the institution and does not currently engage in medical, scientific, legal or academic work*;
 - e. a person who performs a pastoral care role in the community, for example, a Minister of Religion or an Aboriginal elder*;
 - f. at least one person with the knowledge of, and current experience in, the professional care, counselling or treatment of people, for example, a nurse or allied health professional*; and
 - g. at least two academic staff members of the University with current research experience*.
- (11) Each Panel of the Committee also includes the following positions in order to fulfill the Committee's role within the University, as per clause 9 (b):
 - a. at least one nominee of from each Faculty with current research experience, appointed by the Deputy Vice-Chancellor (Research) in consultation with the Executive Dean of the Faculty;

- b. an Indigenous Representative;
- c. at least one academic staff member of the University with current research experience from at least one of the following discipline areas:
 - i. Philosophy;
 - ii. Exercise Science; or
 - iii. Psychology.
- (12) Individual members are allocated to a Panel by the Research Integrity, Ethics and Compliance Unit in consultation with the Presiding Officer and Deputy Presiding Officer/s, taking into account National Statement on Ethical Conduct in Human Research requirements about relative numbers of men and women, internal and external members and any other criteria deemed relevant. Members' preferences in relation to a panel meeting dates are sought to inform decision-making about panel allocation.
- (13) Individual members are appointed to a position on a Panel based on a single membership category listed under either clause 10 or clause 11. Individual members cannot hold positions in multiple membership categories.
- (14) An Alternate Member is inducted for each of the membership categories, as required under the National Statement on Ethical Conduct in Human Research. If one of the substantive members of the Committee cannot attend a meeting then the alternate member in the same category may attend the meeting in their place and participate in the meeting with the same rights of membership as the substantive member.
- (15) All substantive and alternate members are provided with a formal notice of appointment, and may not review any applications until they have completed an induction program.

Term of Office

- (16) The term of appointment for members of the Committee shall be three years.
- (17) Members should provide the Committee with 3 months' notice of their intention to resign. Where extenuating circumstances preclude this, the relevant alternate member will assume the member's position on the Committee until a replacement can be appointed.
- (18) A member's appointment to the Committee may be terminated by the Deputy Vice-Chancellor (Research) following advice from the Presiding Officer.

Appointment of Members

- (19) All members are appointed by the Deputy Vice-Chancellor (Research) in an open and transparent process. Where possible, this will be carried out in consultation with current members, the Presiding Officer, Head of Schools, Executive Deans. If necessary this process may include advertisement and interview.
- (20) All members, including the Chairs, are appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion.
- (21) Re-appointment is by approval from the Deputy Vice-Chancellor (Research).

External Expertise

(22) A panel of experts will be maintained to be called upon to offer advice or clarification of technical/scientific dimensions of an issue relevant to the ethical review of a proposal.

Section 4 - Functions and Responsibilities

(23) The Human Research Ethics Committee shall:

- a. Consider ethical implications of all proposed human research projects submitted to the Committee, that are to be conducted by University staff and postgraduate students (including Honours students) and non-affiliated researchers seeking the Committee's review under the Ethical Review of Multi-Centre Research Scheme and determine whether or not they are acceptable on ethical grounds.
- b. Review each proposal according to the following values:
 - i. Research Merit and Integrity;
 - ii. Justice;
 - iii. Beneficence; and
 - iv. Respect for human beings.
- c. When reviewing and approving research proposals, base all of its comments and requests for clarification or further information, on the National Statement on Ethical Conduct in Human Research, issued by the National Health and Medical Research Council.
- d. Receive and respond to complaints and issues of non-compliance raised by any person in relation to research that has been considered and approved by the Committee.
- e. Submit a quarterly compliance report to the Finance, Audit and Risk Committee, via the Deputy Vice-Chancellor (Research).
- f. Report annually to the National Health and Medical Research Council.
- g. Monitor all approved human research projects until completion so that the Committee may be satisfied that the conduct of research continues to conform with the approved proposal.
- h. Review and ratify executive decisions made by the Presiding Officer (or their nominee) in between meetings.
- i. Retain research applications in the form in which they are approved and maintain a record of all proposed human research projects, so that the following items of information are readily available:
 - i. application identification code or project protocol number;
 - ii. project title;
 - iii. name and contact details of primary contact, co-investigator/s and supervisor/s (if applicable);
 - iv. ethical approval or non-approval with date; and
 - v. date/s designated for reporting.
- j. Establish and maintain communication with the National Health and Medical Research Council and provide access, upon request, to information in the Committee's records.

(24) In carrying out these functions, the Committee shall:

- a. conform with any guidelines and supplementary notes on human research published from time to time by the National Health and Medical Research Council;
- b. take account of local culture and social attitudes in making decisions;
- c. ensure that issues about consent have been fully considered;
- d. ensure that no members of the committee adjudicate on proposals in which they may be personally involved;
- e. ensure that while accepting that there is a duty to advance knowledge by research, the rights of individual patients or subjects of research take precedence over the expected benefits to human knowledge to the Community; and
- f. ensure the two Panels are providing consistent feedback to researchers.

(25) 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 involve review of new full ethics applications.

Governance and Administrative Support

- (26) The Research Integrity, Ethics and Compliance Unit, Office of the Deputy Vice-Chancellor (Research) will provide administrative and secretariat support to the Committee, to the extent required for the Committee to discharge all its obligations under the National Statement on Ethical Conduct in Human Research, and can be called upon for protocol and procedural advice.
- (27) A Governance Officer will be appointed to support the Committee in the administration of its business, including the following responsibilities:
 - a. being the first point of contact for applicants wishing to make application or liaise with the Committee;
 - b. ensuring that proposals are provided to the Committee for consideration;
 - c. ensuring that the decisions of the Committee are conveyed to investigators and teachers in a timely manner;
 - d. ensuring that Committee records are maintained and made available for review by the University and authorised external reviewers;
 - e. ensuring that the University submits the appropriate licence applications, renewals and reports as required; and
 - f. where requested by the Committee, assist with arranging audits and inspections for Committee members relevant to projects approved by the Committee.
- (28) Decisions about allocation of Committee tasks to the Governance Officer/s is the responsibility of the Manager, Research Integrity, Ethics and Compliance, who may seek advice from the Presiding Officer.
- (29) Governance Officer/s who attend Panel meetings have the right of audience and debate, particularly in relation to providing advice on procedural matters and corporate knowledge.

Section 5 - Meetings

Quorum

- (30) Where there is less than full attendance of the minimum membership at a Panel meeting, the Panel Chair should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership categories have been received and considered.
- (31) Members who are unable to attend meetings must send through their apologies and are encouraged to submit their comments on applications to the Panel Chair prior to the meeting, for consideration during the meeting.

Meetings

- (32) Each Panel will meet monthly from February to December, resulting in a meeting each fortnight.
- (33) A schedule of meeting dates and agenda closing dates is posted on the Human Research Ethics Committee website by the beginning of each academic year.
- (34) In exceptional circumstances, the schedule of Panel meetings may be altered by the Presiding Officer, in consultation with the Governance Officer.
- (35) Applications are allocated to a Panel based on their submission date and each Panel's agenda closing date. The Presiding Officer reserves the right to vary this procedure (without disadvantage to applicants) to balance the

workload between Panels.

- (36) If required, the Governance Officer of the Committee may, on behalf of the Presiding Officer, convene an extraordinary meeting of the Committee to review urgent Committee business.
- (37) In those cases where an extraordinary meeting of the Committee cannot be convened, the Governance Officer may circulate proposals and other items of business to the Committee members who shall consider them asynchronously and, in writing, provide comments on applications and any approvals where possible.

Agendas and Minutes

- (38) Agendas are circulated to the Committee one week before the Committee meeting.
- (39) Minutes of the Committee meeting are circulated to Committee members within two weeks following the meeting.

Related Expenses

(40) External members may claim a meeting allowance in accordance with the <u>Compliance Committee Policy</u> - External Members Allowance.

Conflicts of Interest

- (41) Where a member has a perceived or material conflict of interest as described in the University's <u>Conflict of Interest Procedure</u>, they must declare this to the Presiding Officer and at the Committee meeting before discussion of the item of business.
- (42) The Presiding Officer will determine if members with a conflict of interest will remain present for the discussion of the item but not take part in a decision, or if the member must withdraw from the meeting for the discussion of matters that relate to that conflict of interest. Once such members have withdrawn, the remaining members must still constitute a quorum.

Confidentiality

- (43) Matters discussed and papers considered during a Committee meeting are confidential to Committee members and those with the Right of Audience and Debate.
- (44) Specific papers considered during a meeting and records of specific meeting discussions may be shared by the Presiding Officer, or by the Governance Officer with the permission of the Presiding Officer, with authorised Officers of the University who can demonstrate a need to access the relevant information for the performance of their duties.

Variations

(45) Variations to the terms of reference and/or membership of the Committee must be approved by the Deputy Vice-Chancellor (Research).

Status and Details

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