

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

Section 1 - Establishment

Background

(1) The Human Research Ethics Committee is established under the provisions of the <u>National Statement on Ethical</u> <u>Conduct in Human Research 2023</u> (the National Statement).

(2) The Human Research Ethics Committee (the committee) reports through to the Deputy Vice-Chancellor (Research) and, through the Deputy Vice-Chancellor (Research) to the Audit and Risk Committee of the University Council.

(3) There are two panels of the committee, each of which satisfy the membership requirements of a fully constituted committee in accordance with these terms of reference.

Purpose

(4) The committee reviews and issues University approval for research proposals involving human participants to ensure that they are ethically acceptable and follow relevant standards and guidelines. The scope of reviews of the committee include all research involving University investigators in any capacity and includes the reciprocal review of human research ethics applications made to any other third party review panel.

(5) The committee may also undertake externally commissioned human research ethics reviews for third party organisations. These reviews may be undertaken as a community service or on a fee for service basis.

Section 2 - Membership

Committee and panel membership

(6) As per the <u>National Statement</u>, 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 appointed by the Deputy Vice-Chancellor (Research).

(8) Deputy presiding officers are assigned to a specific panel of the committee.

(9) Each panel of the committee comprises the following membership:

- a. The presiding officer as chair and a nominated deputy presiding officer as co-chair.
- b. At least two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution.
- c. At least one person with knowledge of, and current experience in, the professional care or treatment of people, for example, a nurse, counsellor, or allied health professional.

- d. At least one person who performs a pastoral care role in the community, including, but not limited to a First Nations Elder or community leader, a chaplain or a minister of religion or other religious leader.
- e. At least one qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the institution on research-related or any other matters.
- f. At least two academic staff members of the University with current research experience that is relevant to research proposals to be considered at the meetings they attend.

(10) Members may only be appointed to one category of membership at a time. While not ideal or intended, it is permissible for members to serve in the same category on both panels. It is also permissible for members to be formally transferred from one category of membership to another where they meet the relevant eligibility requirements.

(11) Consistent with the <u>National Statement</u>, each panel and any low risk review panel established by the presiding officer should, as far as possible, consist of equal numbers of men and women.

(12) Each panel should consist of at least one third of members external to the University.

(13) 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. Persons identified as experts do not need to be inducted to the committee but are bound by the conflict of interest and confidentiality provisions that apply to any Committee or low risk review panel member.

Low risk review panels

(14) The presiding officer has the discretion to establish panels at faculty, school or research institute level for the purpose of reviewing research applications that meet the <u>National Statement</u> definition of lower risk.

(15) Where there is sufficient quantity of applications from a specific faculty, school or research institute, a low risk review panel may be established, consisting of the following:

- a. A chair, who is, or has been in the last five years, a member of a fully constituted Human Research Ethics Committee, either at the University or another institution.
- b. Two to five persons, with current research experience, recommended by the relevant head of faculty, school or research institute.
- c. In the case of school or research institute based low risk review panels, at least one person with current research experience, not from the school or research institute.

Term of office

(16) The term of appointment for members of the committee or a low risk panel shall be three years.

(17) Members of the committee or a low risk panel are encouraged to provide three months' notice of their intention to resign.

(18) The appointment of a committee member who has a Research portfolio funded workload allocation (usually a presiding officer or deputy presiding officer) can only be terminated by the Deputy Vice-Chancellor (Research) following advice from the Pro Vice-Chancellor Research (Performance and Governance).

(19) An unfunded member's appointment to the committee or a low risk panel may be terminated by the Deputy Vice-Chancellor (Research) following advice from the presiding officer.

(20) Members may be appointed to two consecutive terms.

(21) Members may be appointed to more than two consecutive terms with the express approval of the Deputy Vice-Chancellor (Research).

Appointment of members

(22) Appointments to committee and low risk review panels will be administered by the Research Integrity Unit.

- (23) All committee members are appointed by the Deputy Vice-Chancellor (Research):
 - a. Initial appointment shall be via a merit based recruitment process.
 - b. Reappointment shall be on the recommendation of the presiding officer, or in the case of the presiding officer, on the recommendation of the Pro Vice-Chancellor Research (Performance and Governance).

(24) The chair of a low risk review panel shall be appointed, and re-appointed as appropriate, by the presiding officer. Where the presiding officer seeks to be chair of a low risk review panel, the appointment shall be made by the Pro Vice-Chancellor Research (Performance and Governance), having regard to the presiding officer's workload on the committee.

(25) Low risk review panel members shall be appointed by the Manager, Research Integrity:

- a. Initial appointment shall be via the nomination of the relevant head of faculty, school or research institute.
- b. Reappointment shall be on the recommendation of the presiding officer.

(26) For members of staff seeking appointment to the committee or low risk panel, the recruitment process shall include confirmation of the support of the member's line management to take up, or continue, the member's participation on the committee.

(27) All members of committee and low risk panels are appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion.

(28) There are no specific requirements to be included on the expert panel. Expert panel members are identified as required to provide specialist knowledge and expertise to members of the committee to assist them in the conduct of their duties.

Induction program

(29) All members of committee and low risk review panels are provided with a formal notice of appointment and may not review any applications until they have completed an induction program.

(30) The induction program includes:

- a. for University members of staff, completion within the last three years of the University's eLearning modules for Research Integrity and Human Research Ethics
- b. an induction session with the presiding officer or their delegate. In the case of a new presiding officer not previously a committee member, an induction session with a suitably experienced committee member
- c. attendance at a committee meeting as an observer with no rights of debate, and
- d. provision of and an opportunity for familiarisation with:
 - i. the National Statement
 - ii. these terms of reference.

Presiding officer and deputy presiding officer

(31) The presiding officer shall hold a senior staff member position in the University, holding a position of professor or associate professor. By exception, the Deputy Vice-Chancellor (Research) may appoint a senior lecturer to the position on the basis of demonstrated research and leadership qualities including experience in the review of human research ethics and the application of the <u>National Statement</u>.

(32) A person holding adjunct status with the University is not eligible for consideration as presiding officer or deputy presiding officer. A person holding adjunct status may be appointed as a staff member with an appropriate position fraction in order to meet appointment eligibility.

(33) The presiding officer and deputy presiding officers shall be appointed by the Deputy Vice-Chancellor (Research) of the University for a term of three years. An appointment from the ranks of the committee shall extend that member's term by the full three year period.

(34) The presiding officer and deputy presiding officers shall have a negotiable workload allocation assigned to their positions to ensure that their other responsibilities do not impair the committee's capacity to perform its obligations under the <u>National Statement</u>.

(35) The presiding officer shall have an understanding of the ethical issues involved in research involving human participants. It is desirable that the presiding officer shall also have a strong background in research.

(36) A deputy presiding officer will act in the role of presiding officer in the absence of the presiding officer.

Executive of the Human Research Ethics Committee

(37) The executive of the committee consists of the presiding officer and the two deputy presiding officers.

(38) The committee may nominate an alternate deputy presiding officer for each panel each year.

(39) An alternate deputy presiding officer may act in the role of a deputy presiding officer in the absence of the deputy presiding officer.

Rights of audience and debate

(40) The following position holders have right of audience and debate at meetings of the committee:

- a. Committee support staff, particularly in relation to providing advice on procedural matters and corporate knowledge.
- b. Pro Vice-Chancellor Research (Performance and Governance)
- c. Manager, Research Integrity
- d. Members of the expert panel referenced in Clause 16 above.
- e. Any other member of staff with the approval of the presiding officer.

(41) Persons with rights of audience and debate have no decision-making authority in relation to the business of the committee.

(42) Persons with rights of audience and debate are not required to be inducted to the committee but are bound by the conflict of interest and confidentially provisions that apply to all members.

Section 3 - Functions and responsibilities

(43) The Human Research Ethics Committee shall, either directly or by delegation:

- a. consider ethical implications of all proposed human research projects submitted to the committee, that are to be conducted by University staff, any University student or any researchers seeking the committee's review under the Ethical Review of Multi-Centre Research Scheme and determine whether or not the proposed projects are acceptable on ethical grounds
- b. review each proposal according to the following values articulated in the National Statement:
 - i. research merit and integrity
 - ii. justice
 - iii. beneficence
 - iv. respect for human beings
- c. base all of its comments and requests for clarification or further information, on the requirements of the <u>National Statement</u>
- d. note the review of any low risk human research proposal conducted by a low risk review panel
- e. receive and consider annual reports, variations, extensions and end of project reports so that the committee may be satisfied that the conduct of research continues to conform with the approved proposal
- f. receive and refer to the Research Integrity Unit complaints and issues of non-compliance raised by any person in relation to research that has been considered and approved by the committee
- g. submit a quarterly compliance report to the Audit and Risk Committee, via the Deputy Vice-Chancellor (Research)
- h. report annually to the National Health and Medical Research Council
- i. review and note decisions made by the presiding officer (or their nominee) between meetings, and
- j. at the discretion of the presiding officer, provide education, information and assistance to University academics, researchers and other stakeholders.
- (44) In carrying out the functions of the Human Research Ethics Committee, the presiding officer shall ensure that:
 - a. the operation of the committee conforms with the <u>National Statement</u> and any guidelines and supplementary notes on human research published from time to time by the National Health and Medical Research Council
 - b. adequate expertise is applied to every application considered by the committee or other application review panels, and
 - c. each panel and low risk review panel provides consistent feedback to applicants.

Executive responsibilities

(45) In carrying out the functions of the Human Research Ethics Committee, members of the executive may make the following decisions between committee meetings:

- a. The executive collectively may:
 - i. review and ratify or decline requests for ratification of externally reviewed projects
 - ii. review and accept, reject or decline low risk applications.
- b. Any single member of the executive may review and accept, reject or decline a request for a project extension of time.
- c. Any two members of the executive may review and accept, reject or decline a variation to an existing project.

(46) Any decision made by the executive members under the clause above is binding once made but must be

presented to an HREC panel meeting for formal noting.

Low risk panel and expert panel responsibilities

(47) In carrying out the functions of the Human Research Ethics Committee, a low risk review panel may review and accept, reject or decline low risk applications within the scope of the subject matter expertise of that panel.

(48) Any decision made by a low risk review panel under the clause above is binding once made, but must be presented to a committee meeting for formal noting.

(49) The establishment of a panel of experts is not intended to prevent or discourage clarification or explanation of research proposals being obtained directly from the researcher.

Member responsibilities

(50) Members shall:

- a. thoroughly prepare for meetings by reading applications, reports and documentation provided in meeting agendas
- b. attend scheduled meetings to deliberate on the ethical acceptability of agenda items for approval
- c. actively engage in informed and thorough discussion of matters before the committee
- d. in a timely manner complete actions assigned to them arising from matters before the committee, and
- e. complete training appropriate to the member's position.

(51) Nothing in these terms of reference should exclude a person or panel from referring a matter to the committee for full consideration.

Presiding officer responsibilities

(52) The presiding officer shall impartially guide the operation of the committee, resolve conflicts of interest related to the business of the committee and represent the committee in any negotiations with the management of the University.

(53) Responsibilities of the presiding officer include, but are not limited to:

- a. ensuring that the committee operates in accordance with the principles and requirements of the <u>National</u> <u>Statement</u>, the relevant policies of the University and the agreed committee procedures
- b. overseeing all requirements of committee reporting and reviewing
- c. advising the Pro Vice-Chancellor Research (Performance and Governance) regarding the level of resourcing required by the committee, and
- d. meeting with the Pro Vice-Chancellor Research (Performance and Governance) or other senior management representatives as required to report on the operations of the committee and raise any issues.

Non-attendance

(54) All members must attend 75% of scheduled meetings on an annual basis, subject to mitigating circumstances. Where members cannot attend meetings, apologies must be made in advance to the Research Integrity Unit.

(55) Members who have continued absences from scheduled meetings may be approached by the presiding officer, or nominee, to discuss continuation of membership. If the member opts to remain on the committee or low risk review panel but continues to be absent from the meetings, they may be asked to end their term.

(56) Members who are unable to attend meetings are required to submit their comments on applications prior to the

meeting, for consideration during the meeting. While not ideal, and if appropriate to the application being considered, comments from absent members may be obtained after the meeting.

Committee and low risk panel support

(57) The Research Integrity Unit will provide administrative and secretariat support so that the committee can discharge its obligations. The Research Integrity Unit can also be called upon for protocol and procedural advice.

(58) It is the responsibility of the Manager, Research Integrity to allocate committee tasks to the team members of the Research Integrity Unit. This activity will be undertaken in consultation with the presiding officer.

(59) Research Integrity Unit team members will support the committee or low risk panel in the conduct 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 or low risk panel
- b. providing advice to all stakeholders on governance and administrative matters, including confidentiality and conflicts of interest
- c. ensuring that proposals are provided to the appropriate committee or low risk panel for consideration
- d. ensuring that the decisions are conveyed in a timely manner
- e. ensuring that records are maintained and made available for review by the University and authorised external reviewers
- f. ensuring that the University submits the appropriate license or accreditation applications, renewals and reports as required
- g. where requested, assist with arranging audits and inspections, and
- h. retain research applications in the form in which they are approved and maintain a record of all proposed 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
 - v. date(s) designated for reporting.

Section 4 - Meetings

Attendance conformance with the National Statement

(60) Only meetings where the full complement of members set out in clause 10 are present is a meeting conformant with the <u>National Statement</u>. Only meetings so conformant can make decisions in conformance with the <u>National Statement</u>.

(61) Where there is less than conformant attendance at a meeting, the meeting chair must be satisfied, in every instance, before a decision is reached, that:

- a. adequate expertise has been applied to the application being considered, and
- b. reasonable efforts have been made to receive and consider the views of those absent, before a decision is made.

(62) Where the chair is not satisfied that a decision can be made, that item of business is to be deferred.

(63) Notwithstanding the provisions above, a meeting of the committee cannot proceed unless the following members are present:

- a. One of the presiding officer or a deputy presiding officer.
- b. Three members of the panel from the membership requirements of clause 10 b-e above.
- c. One academic staff member from the membership requirements of clause 10 f above.

(64) A quorum for a low risk review panel meeting shall be:

- a. a person meeting the eligibility requirements to be a low risk review panel chair, and
- b. any one other member of the low risk review panel.

Meetings

(65) Each HREC panel will meet monthly from February to December, resulting in a committee meeting approximately every two weeks.

(66) A schedule of committee meeting dates and agenda closing dates will be posted on the Human Research Ethics Committee website by the beginning of each academic year.

(67) In exceptional circumstances, the schedule of the committee meetings may be altered by the presiding officer, in consultation with the relevant staff in the Research Integrity Unit.

(68) Schedules for meetings of the low risk review panels will be developed on an as needs basis in consultation with the presiding officer and/or the relevant low risk review panel chair.

(69) Applications are allocated to the committee or a low risk review panel based on their submission date and each HREC panel's agenda closing date. The presiding officer reserves the right to vary this procedure to balance the workload between the various review bodies.

(70) Extraordinary meetings of the committee may be convened during peak workload or to review urgent committee business.

(71) Meetings by flying minute are permissible at the discretion of the presiding officer. Meeting by flying minute would normally be reserved for urgent but uncomplicated decision making where it is not anticipated that extensive panel discussion and debate will be required. In these cases, proposals and other items of business will be circulated to the committee members who shall consider them asynchronously and, in writing, provide comments on applications or other matters of business.

Agendas and minutes

(72) Agendas are circulated to the members one week before the meeting.

- (73) Minutes of meetings are confirmed in draft by the meeting chair within one week of the meeting.
- (74) Outcomes of meeting decisions are advised within one week of the meeting.
- (75) Minutes of the meeting are circulated to members within three weeks following the meeting.

Related expenses

(76) External members may claim a meeting allowance in accordance with the Compliance Committee Policy - External Members Allowance.

Conflicts of interest

(77) Where a member has a perceived or actual conflict of interest as described in the University's Conflict of Interest Procedure, they must declare this to the chair at the meeting before discussion of the item of business.

(78) The meeting chair will determine if members with a conflict of interest may 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

(79) Confidential matters relating to the committee include, but are not limited to:

- a. the content and nature applications before the committee
- b. the deliberations of members during consideration of meeting business
- c. the private information of persons internal and external to the University contained within meeting papers
- d. arrangements involving third parties, and
- e. information relating to complaints, misconduct or investigations.

(80) Agenda items considered during a meeting and records of specific meeting discussions may be shared by the presiding officer, or by the Manager, Research Integrity, with authorised officers of the University who can demonstrate a need to access the relevant information for the performance of their duties.

Variations

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

Section 5 - Glossary

(82) For the purposes of this document:

- a. External member means a member appointed to the committee in accordance with section 5.1.30 of the <u>National Statement</u>, who is not:
 - i. a current student
 - ii. a member of the University Council or a committee of the University Council
 - iii. an employee of the University or a controlled entity of the University.

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Unit Head	Elizabeth Harangozo Manager, Research Integrity 02 6051 9356
Author	Elizabeth Harangozo Manager, Research Integrity 02 6051 9356
Enquiries Contact	Research Integrity Unit 02 6933 4322