

Human Research Ethics Committee

TERMS OF REFERENCE

1. TITLE OF COMMITTEE

Human Research Ethics Committee

2. ESTABLISHMENT

The Human Research Ethics Committee is established under Part 3 Section 15 of the [Charles Darwin University Act 2003](#).

3. FUNCTIONS AND RESPONSIBILITIES

The Human Research Ethics Committee operates in accordance with the [National Statement on Ethical Conduct in Human Research](#). The Committee is responsible for the ethical design, review and conduct of human research conducted by researchers and students under the auspices of the University.

The functions and responsibilities of the Human Research Ethics Committee, are to:

- Consider the ethical aspects and implications of proposals to conduct research involving humans that involves more than a low risk and proposals to undertake Indigenous Research;
- Ensure that researchers are appropriately qualified in planning, conducting and reporting research that is relevant to the proposal, and students are appropriately supervised, to conduct research;
- Promote and provide oversight for the proper arrangements for security and disposal of data collected in the course of research;
- Certify that research protocols satisfy the ethical standards and codes presented in the [National Statement on Ethical Conduct in Human Research](#) and the [Australian Code for the Responsible Conduct of Research](#);
- Make recommendations or impose conditions on research proposals to ensure they meet requirements and are ethically acceptable;
- Identify and manage all conflicts of interest that may affect the research or approval process in accordance with the University's procedures;
- Monitor ongoing activity including annual reports, variations and adverse incident reports that arise during the implementation of approved research protocols;
- Impose requirements for the amendment of an approved protocol or suspend an approved protocol if necessary;
- Ensure decisions are transparent, consistent, and promptly communicated;
- Oversee and regularly assess the University's ethical review processes, including the criteria for allocating research to different levels of review – Panel Review and Executive Review;
- Receive appeals against a decision or conduct of Committee or Panel members;
- Provide advice on any complaint regarding the approval of proposals or the conduct of approved research protocols;
- Hold confidential all deliberations, discussions and all information in proposals not in the public domain; and

- Monitor, review and make recommendations on Governance Documents about research involving human participants.

For research that carries only low risk, the University will establish a Human Research Ethics Panel under Panel Review - Category PR, to:

- Consider the ethical aspects and implications of proposals to conduct research involving humans that carries only low risk;
- Ensure that researchers are appropriately qualified in planning, conducting and reporting research that is relevant to the proposal, and students are appropriately supervised, to conduct research;
- Certify that research protocols satisfy the ethical standards and codes presented in the [National Statement on Ethical Conduct in Human Research](#) and the [Australian Code for the Responsible Conduct of Research](#);
- Approve low risk proposals that meet the requirements of the [National Statement on Ethical Conduct in Human Research](#) and are ethically acceptable;
- Refer proposals that involve more than negligible or low risk to the Human Research Ethics Committee for consideration; and
- Report the outcomes of all proposal considerations to the Human Research Ethics Committee.

For research that carries only negligible risk, the Chair and Deputy Chair/s under Executive Review - Category ER, will review and approve proposals, protocol variations, reciprocal proposals and exempt research requests that meet the requirements of the [National Statement on Ethical Conduct in Human Research](#) and are ethically acceptable.

4. MEMBERSHIP

Membership of the Human Research Ethics Committee will consist of a minimum of eight (8) people and comprise the following:

- Chair;
- Pro Vice-Chancellor Indigenous Leadership (or delegate); and
- At least two (2) lay people of each gender, who have no affiliation with the University and do not currently engage in medical, scientific, legal or academic work;
- At least one (1) person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
- At least one (1) person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
- At least one (1) lawyer who is not engaged to advise the institution where possible; and
- At least two (2) people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

Membership of a Human Research Ethics Panel will comprise the following:

- Chair (either the Chair or a Deputy Chair of the Human Research Ethics Committee); and
- At least three (3) people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

The Human Research Ethics Committee/Panel members are appointed by the Vice-Chancellor on the recommendation of the Deputy Vice-Chancellor, Research and Innovation for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion. Members will be drawn from an inducted pool of members who have relevant experience and/or expertise to address the ethical

issues arising from the research it is likely to consider and at least one (1) person experienced in reflecting on and analysing ethical decision-making.

Ordinary members and at least one (1) alternate member wherever possible will be appointed to participate in Committee and Panel business in the absence of the ordinary member and not as the representative of the corresponding ordinary member.

The Committee/Panel will endeavour to maintain gender balance in the membership and no more than two-thirds of the members will be staff of the University.

5. CHAIR

The Chair and one (1) or more Deputy Chairs are appointed by the Vice-Chancellor on the recommendation of the Deputy Vice-Chancellor, Research and Innovation.

The Chair will preside over Human Research Ethics Committee meetings. A Deputy Chair will preside over Committee meetings if the Chair is absent or unable to perform the duties of the Chair.

Deputy Chairs will preside over Human Research Ethics Panel meetings.

6. SECRETARY

A Research Ethics Coordinator will perform the functions of secretary at Human Research Ethics Committee meetings and Human Research Ethics Panels meetings where necessary.

7. TERM OF OFFICE

The Chair will hold office for three (3) years and may be reappointed.

The Pro Vice-Chancellor, Indigenous Leadership will hold office for the tenure of their substantive position.

Ordinary members will hold office for a term of two (2) years and may be reappointed, to ensure a mix of new and experienced members.

Members who cannot participate regularly must consider resigning.

8. QUORUM

The quorum for a Human Research Ethics Committee meeting is five (5) members in attendance.

The quorum for a Human Research Ethics Panel meeting is three (3) members in attendance.

Recommendations may be made at an inquorate meeting but must be approved by a quorate meeting before promulgation.

9. MEETINGS

The Human Research Ethics Committee will meet a minimum of six (6) times per year.

A Human Research Ethics Panel will be formed and meet as required. Members may participate in a meeting using any appropriate communications technology.

As far as possible, each Human Research Ethics Committee meeting will enable at least one (1) ordinary member in each category to attend. With the prior approval of the Chair, a member may participate by providing written commentary on any agenda item.

10. RESOLUTIONS OF THE COMMITTEE

Matters requiring a resolution will be determined by consensus of the members present wherever possible. In the event that a motion is moved, it will be carried if it is supported by a majority of the members present and voting.

The Chair of a meeting has a vote and in the case of an equality of votes a casting or deliberative vote.

11. AGENDA

A written agenda and supporting documents will be distributed prior to each meeting.

12. REPORTING

The Chair will provide an annual report to the Vice-Chancellor detailing the work of the Human Research Ethics Committee and to the National Health and Medical Research Council in accordance with their requirements.

13. RELEVANT DEFINITIONS

In the context of this document:

Document History and Version Control

Last amendment:	May 2019
Sponsor:	Deputy Vice-Chancellor, Research and Innovation
Contact Officer:	Chair, Human Research Ethics Committee

Version	Date Approved	Approved by	Brief Description
1.00	25 Mar 2008	Vice-Chancellor	Creation of original document and upload to CDU website.
1.01	18 Mar 2013	Governance	<ul style="list-style-type: none"> • Converted document to current template • Assigned document number • Changed DVCR to DVC in line with current position title • Minor changes to wording, formatting and grammar • Addition of hyperlinks
1.02	19 Sep 2017	Governance	<ul style="list-style-type: none"> • Conversion to new Governance template due to new University branding • Updated hyperlinks • Replaced shall with will
2.00	01 May 2019	Vice-Chancellor	Major revision in line with updated legislation