

Human Research Ethics Committee Terms of Reference

Section 1 - Establishment

(1) The Charles Darwin University (CDU) Human Research Ethics Committee (CDU-HREC) is established pursuant to powers under sections 6 and 15 of the Charles Darwin University Act 2003.

Section 2 - Functions and Responsibilities

(2) The CDU-HREC operates in accordance with the National Statement on Ethical Conduct in Human Research (the Statement) and the Australian Code for the Responsible Conduct of Research (the Code). 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.

(3) The functions and responsibilities of the CDU-HREC are to:

- a. consider the ethical aspects and implications of proposals to conduct research involving humans that involves greater than a low risk;
- b. consider the ethical aspects and implications of all proposals to undertake First Nations research;
- c. 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;
- d. promote and provide oversight for the proper arrangements for security and disposal of data collected during research;
- e. certify that research protocols satisfy the ethical standards and codes presented in the Statement;
- f. make recommendations or impose conditions on research proposals to ensure they meet requirements and are ethically acceptable;
- g. identify and manage all conflicts of interest that may affect the research or approval process in accordance with the University's policies and procedures;
- h. monitor ongoing activity including annual reports, variations and adverse incident reports that arise during the implementation of approved research protocols;
- i. impose requirements for the amendment of an approved protocol or suspend an approved protocol if necessary;
- j. ensure decisions are transparent, consistent, and promptly communicated;
- k. oversee and regularly assess the University's ethical review processes, including the criteria for allocating research to different levels of review;
- l. receive appeals against a decision or conduct of CDU-HREC or Panel members;
- m. provide advice on any complaint regarding the approval of proposals or the conduct of approved research protocols;
- n. hold confidential all deliberations, discussions and all information in proposals not in the public domain; and
- o. monitor, review and make recommendations on governance documents about research involving human

participants.

(4) For research that carries only low risk, the University will establish a Human Research Ethics Panel (a Panel) to:

- a. consider the ethical aspects and implications of proposals to conduct research involving humans that that carries only low risk;
- b. 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;
- c. certify that research protocols satisfy the ethical standards and codes presented in the Statement and the Code;
- d. approve low risk proposals that meet the requirements of the Statement and are ethically acceptable;
- e. refer proposals that involve more than negligible or low risk to the CDU-HREC for consideration; and
- f. report the outcomes of all proposal considerations to the CDU-HREC.

(5) For research that carries only negligible risk, the Chair and Deputy Chair(s) will review and approve proposals, protocol variations, reciprocal proposals and exempt research requests that meet the requirements of the Statement and are ethically acceptable.

Section 3 - Membership

(6) Membership of the CDU-HREC will consist of a minimum of eight people and comprise the following:

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

(7) Membership of a Panel will comprise the following:

- a. a Chair (either the Chair or a Deputy Chair of the CDU-HREC); and
- b. at least three people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

(8) CDU-HREC and Panel members are appointed by the Vice-Chancellor 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 people 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 person experienced in reflecting on and analysing ethical decision-making.

(9) A person will be considered inducted once they have undertaken an induction from the Chair or a Deputy Chair that includes their expected duties and responsibilities as a CDU-HREC or Panel member and an assurance that they are familiar with the Statement.

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

Section 4 - Chair and Deputy Chair

(11) The Chair is appointed by the Vice-Chancellor.

(12) The Chair of the CDU-HREC will:

- a. hold a senior position (Professor or Associate Professor) at the University;
- b. be appointed in addition to other members;
- c. normally preside at all meetings of the CDU-HREC;
- d. impartially guide the operation of the CDU-HREC, resolving conflicts of interest related to the business of the CDU-HREC; and
- e. represent the CDU-HREC in any negotiations with the University's management or the Organisation's management.

(13) The Vice-Chancellor will appoint one or more Deputy Chairs from the membership of the CDU-HREC. A Deputy Chair will preside over CDU-HREC meetings if the Chair is absent or unable to perform the duties of the Chair.

(14) Deputy Chairs will preside over Panel meetings.

Section 5 - Secretary and Resources

(15) The Office of Research and Innovation will provide the functions of the Secretary at meetings and all necessary administrative services to the CDU-HREC and its members.

(16) Committee members will be provided with access to all resources they reasonably require to fulfil their duties as a Committee member.

Section 6 - Terms of Office

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

(18) The Deputy Vice-Chancellor, First Nations Leadership will hold office for the tenure of their substantive position.

(19) All members, other than the Chair and the Deputy Vice-Chancellor, First Nations Leadership, are appointed for a term of two years. At the end of their term, the position will be advertised by the Office of Research and Innovation. Current members may reapply.

(20) Reappointed members can serve a maximum of three consecutive terms. On reappointment of the third term, preference will be given to new applicants of equal qualifications, availability, and commitment. It is acceptable for members to subsequently be re-appointed to the CDU-HREC after a period of three years' absence. Appointments to the CDU-HREC should meet the University's Equity, Diversity and Inclusion Policy wherever possible.

(21) Replacement of members will be phased to ensure the maintenance of a quorum and expertise on the CDUHREC. Where a replacement member is not able to commence an appointment at the end of a current member's term, the current member will be asked to remain on the CDU-HREC until the replacement has been appointed and inducted.

(22) Members who do not attend three consecutive meetings, or a minimum of half of the annual scheduled CDUHREC meetings without approved leave of absence will have their membership terminated.

(23) The office of a member of the CDU-HREC becomes vacant if the member:

- a. dies;
- b. absents themselves from four consecutive meetings of the CDU-HREC of which reasonable notice has been given to the member personally or in the ordinary course of post, except on leave granted by the CDUHREC or unless, before the expiration of four weeks after the last of those meetings;
- c. becomes a mentally incapacitated person;
- d. is convicted of an offence that is punishable by imprisonment for 12 months in any Australian jurisdiction;
- e. resigns the office by instrument in writing addressed to the CDU-HREC; or
- f. completes a term of office and is not reappointed.

(24) The Chair is taken to have vacated their office if they:

- a. resign by instrument in writing addressed to the CDU-HREC, or
- b. cease to be a member of the CDU-HREC.

Section 7 - Quorum

(25) A quorum for a CDU-HREC meeting is five members in attendance.

(26) A quorum for a Panel meeting is three members in attendance.

(27) When a member is unable to attend a CDU-HREC meeting due to unavoidable circumstances, the CDU-HREC may use video conferencing or web-conferencing to ensure a quorate meeting.

(28) Members unable to attend meetings must advise the Chair as early as possible and may forward comments on the business before the meeting.

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

Section 8 - Meetings

(30) The CDU-HREC will meet a minimum of six times per year.

(31) Panels are formed and meet as required. Members may participate in a meeting using any appropriate communications technology.

(32) As far as possible, each CDU-HREC meeting will enable at least one 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.

(33) Committee members must fully prepare for each meeting and read all documentation in advance of the meeting.

(34) Committee members must make every reasonable effort to attend each meeting.

(35) Minutes of the meeting will be circulated to all the members as soon as practicable after each meeting. The minutes will be confirmed at the subsequent CDU-HREC meeting.

(36) The CDU-HREC may invite people with specific expertise to provide advice as required. Any experts so invited are subject to CDU-HREC confidentiality requirements.

(37) The CDU-HREC will ensure that records are maintained, including:

- a. a register of all applications to the CDU-HREC and any Panels, including the outcomes of deliberations regarding those applications; and
- b. minutes that record decisions and other aspects of the CDU-HREC and Panel meetings.

Section 9 - Decisions and Resolutions of the Committee

(38) Decisions will be based on a thorough, fair and inclusive process of discussion and deliberation by CDU-HREC or Panel members and will be made only by those present throughout the discussion.

(39) Decisions should be based on consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the CDU-HREC or Panel will explore with the applicant(s) ways of modifying the project or activity that may lead to consensus. If consensus is still not achieved, the CDU-HREC or Panel should only proceed to a majority decision after members have been allowed a period of time to review their position followed by a further discussion.

(40) The Chair has a vote and, in the case of an equality of votes, the deciding vote.

Section 10 - Agenda

(41) A comprehensive agenda and all associated documentation will be distributed ten calendar days before the meeting. Members will be notified in writing of the location and availability of meeting materials.

(42) Only in exceptional circumstances and with the Chair's written permission will late papers or the tabling of papers be accepted.

(43) All papers must be submitted to the Office of Research and Innovation by the specified submission deadline and no less than ten working days before the distribution of the agenda and associated documentation.

Section 11 - Conflicts of Interest

(44) Conflict of interest arises when a member has an interest in a matter that may be reasonably construed as having the potential to influence the impartiality of that member in relation to that matter. The conflict of interest may be reasonably perceived, potential or actual conflict of interest. Members must declare conflicts of interest to the Chair who will exercise discretion and give direction to resolve the conflict of interest.

(45) Conflicts of interest are to be resolved in line with the University's Conflict of Interest Policy.

(46) If any member is in doubt as to whether conflict may exist, they are encouraged to seek advice from the Chair.

(47) The Chair must not preside over matters in which they have a conflict of interest.

(48) For decision-making, members with a conflict of interest must withdraw from the meeting for the discussion of the particular agenda item. Once such members have withdrawn, the remaining members must constitute a quorum.

Section 12 - Review of Decisions and Complaints

(49) The CDU-HREC will follow the University's approved procedures for the fair resolution of disagreements between CDU-HREC members, between the CDU-HREC and investigators or teachers and between the CDUHREC and any organisation for which it acts.

Section 13 - Reporting

(50) The CDU-HREC is responsible to the Vice Chancellor and reports to the Vice Chancellor via the Academic Board as the nominated representative of the University on all matters affecting human research ethics at the University.

(51) The CDU-HREC must submit a written report on its activities at least annually to the Vice Chancellor via the Academic Board for presentation to the University Council. The report includes information on:

- a. Numbers and types of projects assessed and approved or rejected;
- b. Activities and actions that have supported the educational needs of CDU-HREC members;
- c. Administrative and other difficulties being experienced; and
- d. Any matters that may affect the University's ability to maintain compliance with the Statement, and any recommendations to address these matters.

(52) The CDU-HREC is also held accountable for its activities through the provision of annual compliance and activity reports to the National Health and Medical Research Council (NHMRC), the national accreditation body.

(53) The Chair will provide an annual report to the Vice-Chancellor detailing the work of the CDU-HREC and to the National Health and Medical Research Council in accordance with their requirements.

Section 14 - Compliance, Monitoring and Review

(54) The University will regularly monitor and review its compliance with the Statement by:

- a. ensuring the Terms of Reference of the CDU-HREC are reviewed by the Vice Chancellor every four years, at a minimum following the external review of the CDU-HREC, or as required;
- b. conducting an annual review of the operation of the CDU-HREC; and
- c. conducting an annual review of the effectiveness of the CDU-HREC's processes regarding complaints and non-compliance.

Section 15 - New Section

(55) Non-compliance with Governance Documents is considered a breach of the Staff Code of Conduct or the Student Code of Conduct, as applicable, and is treated seriously by the University. Reports of concerns about non-compliance will be managed in accordance with the applicable disciplinary procedures.

(56) All staff members have an individual responsibility to raise any suspicion, allegation or report of fraud or corruption in accordance with the Fraud and Corruption Control Governance Framework, Fraud and Corruption Control Policy and Whistleblower reporting (Improper Conduct) Procedures.

Status and Details

Status	Historic
Effective Date	29th September 2021
Review Date	29th September 2023
Approval Authority	University Secretary
Approval Date	8th July 2022
Expiry Date	28th July 2022
Unit Head	Steve Rogers Pro Vice-Chancellor Research and Innovation +61 8 89466890
Author	Matthew Giakoumatos Policy and Governance Officer
Enquiries Contact	Governance