Human Research Ethics Committee Terms of Reference

Section 1 - Establishment

(1) The Human Research Ethics Committee (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 HREC operates in accordance with the National Statement on Ethical Conduct in Human Research 2023 (the Statement) and the Australian Code for the Responsible Conduct of Research, 2018 (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 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 HREC or Low Risk Committee 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 lower risk, as defined in chapter 2.1 of the Statement, the University will establish a Low Risk Committee 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 HREC for consideration; and
f. report the outcomes of all proposal considerations to the HREC.

(5) The Low Risk Committee will meet once a month and consist of the HREC Chair and/or Deputy Chair(s) and will include at least 2 members of the committee in attendance. The Low Risk Committee will review and approve lower risk proposals.

(6) An Executive Review Pathway monitors approved projects. The Chair and/or Deputy Chair(s) will review protocol variations, reciprocal proposals, annual and final reports, and exempt research requests that meet the requirements of the Statement and are ethically acceptable.

(7) The HREC must review all proposals that carry a higher risk, as defined in the Statement, or research involving any of the following groups of participants:

a. Participants with cognitive impairment;
b. First Nations Participants;
c. Highly dependent on medical care;
d. Illegal activities;
e. Pregnant women/foetus, dependent/unequal status;
f. Often children; and
g. Research being conducted overseas (outside of Australia).

(8) For First Nations, defined as any research that relates to, or may have the potential to impact, the collective rights and interests of First Nations peoples' lands, waters, cultures and histories, the University will establish a First Nations subcommittee to:

a. consider the ethical aspects and implications of proposals to conduct research involving First Nations participants, data or knowledge;
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, the Code and additional ethical principles for First Nations research as described in the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020) (AIATSIS Code);
d. Consider acceptability of the proposed research with the HREC guidelines for reviewing and supporting First Nations Research; and
e. report the outcomes of all proposal considerations to the HREC.

(9) The First Nations sub-committee will meet the week before the scheduled HREC meeting and will consist of the Deputy Vice-Chancellor First Nations Leadership or delegate and will include at least 2 First Nations members of the committee in attendance. The First Nations Sub Committee will review and advise the HREC on all First Nations proposal. The HREC will receive the sub-committee recommendations for consideration at the scheduled HREC meeting.

Section 3 - Membership

(10) Membership of the 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.

(11) Membership of a Low Risk Committee will comprise the following:

a. a Chair (either the Chair or a Deputy Chair of the 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.

(12) All members of the Low Risk Committee will be inducted as committee members and will be familiar with the Statement and the Code.

(13) Membership of the First Nations Committee will comprise:

a. a Chair (either Deputy Vice-Chancellor First Nations Leadership, the Chair or a Deputy Chair of the HREC);
b. at least 2-3 First Nations members of the committee; and
c. to uphold and respect First Nations self-determination, the Chair of the First Nations Sub-Committee should be a First Nations person, wherever possible. If the Chair duties are undertaken by a non-First Nations member of the HREC as temporary chair, they will not have a vote.

(14) All members of the First Nations committee will be inducted as committee members and will be familiar with the Statement, the Code and the AIATSIS Code.

(15) HREC, Low Risk Committee, and First Nations Committee 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.

(16) Appointments to the HREC should meet the Equity, Diversity and Inclusion Policy wherever possible.

(17) A person will be considered inducted once they have undertaken an induction from the Chair, the Research Ethics and Integrity Coordinator, or a Deputy Chair that includes their expected duties and responsibilities as an HREC, Low Risk Committee, or First Nations Committee member.

(18) Ordinary members and at least one alternative member wherever possible will be appointed to participate in HREC and sub-committee business. This is to ensure adequate membership to maintain quorum in the absence of an ordinary member.

(19) The HREC, the Low Risk Committee, and the First Nations Committee will endeavour to maintain gender balance in the membership and no more than two-thirds of the members will be staff of the University.

(20) In accordance with member responsibilities outlined in the Statement (chapter 5.2.22) HREC and subcommittee members must:

a. become and remain familiar with the National Statement, and consult other guidelines and information relevant to the review of specific research proposals;
b. prepare for and attend scheduled meetings of the review body or, if unavailable, provide assessment on the ethical acceptability of research proposals before meetings, subject to institutional policies on absences; and
c. attend continuing education or training programs in research ethics at least every three years, or more frequently if provided by the institution or review body.

Section 4 - Chair and Deputy Chair

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

(22) The Chair of the HREC will:

a. hold, or have held, a senior position at a university or other research organisation, and have suitable experience in a range of relevant methodologies;
b. be appointed in addition to other members;
c. normally preside at all meetings of the HREC;
d. impartially guide the operation of the HREC, resolving conflicts of interest related to the business of the HREC; and
e. represent the HREC in any negotiations with the University’s management or the Organisation’s management.

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

(24) The Chair or Deputy Chairs will preside over Low Risk Committee and First Nations Sub-committee meetings.

(25) If the Chair and Deputy Chairs are unavailable on the day of a scheduled HREC meeting, or low risk committee meeting, the Research Ethics and Integrity Coordinator will preside as interim Chair, with no voting rights.

Section 5 - Secretary and Resources

(26) The Office of Research and Innovation will provide the functions of the Secretary at meetings and all necessary administrative services to the HREC, its sub-committees, and their members.

(27) 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

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

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

(30) Appointed members hold office for a term of three years. At the end of their term, the position will be advertised by the Office of Research and Innovation. Current members may reapply.

(31) Appointed 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.

(32) It is acceptable for members to subsequently be re-appointed to the HREC after a period of three years' absence.

(33) Replacement of members will be phased to ensure the maintenance of a quorum and expertise on the HREC. 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 HREC until the replacement has been appointed and inducted.

(34) Members who do not attend three consecutive meetings, or a minimum of half of the annual scheduled HREC or sub-committee meetings without approved leave of absence may have their membership terminated.

(35) On the advice of the Chair, the Vice-Chancellor may terminate an individual's membership of the HREC if the Chair determines that their continued membership is not constructive to the operation and functioning of the HREC.

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

a. they resign by instrument in writing addressed to the HREC;
b. they cease to be a member of the HREC; or
c. the Vice-Chancellor terminates their appointment.

Section 7 - Quorum

(37) A quorum for a HREC meeting is eight members in attendance, with at least one member from each category present.

(38) A quorum for a Low Risk meeting is three members in attendance in addition to the Chair.

(39) A quorum for a First Nations subcommittee meeting is two members in attendance in addition to the Chair.

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

(41) Members unable to attend meetings must advise the Chair or the Research Ethics and Integrity Coordinator as early as possible and may forward comments on the business day before the meeting.

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

Section 8 - Meetings

(43) The HREC will meet a minimum of seven times per year.

(44) The Low Risk Committee wil meet monthly.

(45) The First Nations Sub Committee will meet seven times per year, the week prior to the scheduled HREC meeting.

(46) As far as possible, each 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, however written commentary will not count towards quorum if the member is not present.

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

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

(49) 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 HREC meeting.

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

(51) The HREC will ensure that records are maintained, including:

a. a register of all applications to the HREC and any Low Risk Committees, including the outcomes of deliberations regarding those applications; and
b. minutes that record decisions and other aspects of the HREC and Low Risk Committee meetings.

Section 9 - Decisions and Resolutions of the Committee

(52) Decisions will be based on a thorough, fair and inclusive process of discussion and deliberation by HREC or Low Risk Committee members and will be made only by those present throughout the discussion.

(53) Decisions should be based on consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the HREC or Low Risk Committee 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 HREC or Low Risk Committee 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.

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

(55) The Low Risk Committee may decide to escalate review of a project considered higher risk, for review by the HREC.

(56) The First Nations sub committee will advise the HREC on all First Nations projects. The decision of the HREC must be based on the recommendations and advise of the First Nations sub committee.

(57) Decisions can only be made at a quorate meeting. If quorum is not met, or is lost during a meeting due to a member leaving early, no decisions can be made. In this case, the committee may choose to either postpone the meeting agenda and hold an additional interim meeting when quorum can be met, or may decide to continue

discussions with minutes to be circulated to all HREC members to vote, after the meeting concludes.

Section 10 - Agenda

(58) 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.

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

(60) 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

(61) 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.

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

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

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

(65) 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

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

Section 13 - Reporting

(67) The 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.

(68) The HREC must submit a written report on its activities at least annually to the Research Committee for presentation to the Vice-Chancellor and Academic Board. 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 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.

(69) The 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.

(70) The Chair will provide an annual report to the National Health and Medical Research Council in accordance with their requirements.

Section 14 - Compliance, Monitoring and Review

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

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

Section 15 - Non-compliance

(72) Non-compliance with Governance Documents is considered a breach of the Code of Conduct - Employees or the Code of Conduct - Students, 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 outlined in the Charles Darwin University and Union Enterprise Agreement 2025 and the Code of Conduct - Students.

(73) Complaints may be raised in accordance with the Complaints and Grievance Policy and Procedure - Employees and Complaints Policy - Students.

(74) 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 Policy and Whistleblower Reporting (Improper Conduct) Procedure.

Status and Details

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Committee Chair	Steve Rogers Deputy Vice-Chancellor Research and Community Connection +61 8 89466890
Author	Matthew Giakoumatos Policy and Governance Officer 08 8946 7383
Enquiries Contact	Human Research Ethics Human Research Ethics team Research and Innovation

Glossary Terms and Definitions

"University" - Charles Darwin University, a body corporate established under section 4 of the Charles Darwin University Act 2003. The University is comprised of the various faculties, CDU TAFE, organisational units, and formal committees, including the governing University Council and Academic Board.