Research Ethics Policy

Section 1 - Preamble

(1) Charles Darwin University ('the University', 'CDU') promotes and fosters excellence and innovation in research at or above world standard.

(2) The University is committed to research that is conducted responsibly, ethically and with integrity, and that complies with relevant codes and legislation.

Section 2 - Purpose

(3) The purpose of this policy is to:

a. outline the University's policy on human research ethics, animal research ethics, and institutional biosafety;
b. establish the mechanisms underpinning the ethical conduct of all forms of research at the University and the processes for objective and rigorous ethical review of research;
c. assist researchers to consider and meet their ethical responsibilities with regards to all aspects of their research and guide them on their obligations relating to ethical review processes and pathways;
d. inform the University community of institutional responsibilities regarding ethics; and
e. articulate the responsibilities of those involved in ethical reviews and related protocols.

Section 3 - Scope

(4) This policy applies to:

a. all staff, including sessional staff, employed by the University or any of its controlled entities, with the exception of the Menzies School of Health Research (Menzies) (see below);
b. all persons, including adjunct staff and honorary staff, engaged in research at the University or under the auspices of the University or any of its controlled entities;
c. all students of the University who engage in research and/or research related activities while enrolled at the University; and
d. the ethics committees of the University, including the Human Research Ethics Committee (HREC), the Animal Ethics Committee (AEC), the Top End Human Research Ethics Committee (TEHREC), and the Darwin Regional Institutional Biosafety Committee (DRIBC), and the members of those committees.

(5) This policy does not apply to staff employed by Menzies unless they are engaged in research under the auspices of the University, or unless they are supervising a Higher Degree by Research (HDR) candidate enrolled at the University. Staff employed by Menzies must follow the relevant research ethics policies and processes of that institution.

This policy document may be varied, withdrawn or replaced at any time. Printed copies, or parts thereof, are regarded as uncontrolled and should not be relied upon as the current version. It is the responsibility of staff printing this document to always refer to the Governance Document Library for the latest version.

Section 4 - Policy

(6) The Australian Code for the Responsible Conduct of Research, 2018 (the Code) articulates the broad principles that characterise an honest, ethical and conscientious research culture.

(7) The Code states that the primary responsibility for ensuring the integrity of research lies with individual researchers and the University.

(8) The conduct of research involving the participation of humans must comply with the provisions of the National Statement on Ethical Conduct in Human Research 2023 (the National Statement).

(9) The conduct of research or teaching involving animals must comply with the requirements of the Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition 2013 and other legislative requirements of the states and territories in which the research takes place.

(10) The University must comply with the Gene Technology Act 2000 (Cth) and associated regulations.

(11) Researchers may have additional ethics burdens placed upon them by professional codes of ethics in their disciplines, or when conducting clinical trials. Where the discipline and the Code, National Statement or other legislation do not align, researchers must adhere to the overriding standard. If neither standard overrides the other, the more stringent standard applies. Contact the Ethics team for advice.

Responsibilities

Responsibilities of the University

(12) The University will ensure that:

a. all members of the University community are informed of their obligations to conduct ethical research;
b. all research is conducted ethically and complies with all current ethical codes and legislation;
c. all approved research is designed to minimise the risk of research posed to participants, animals, researchers, the University and the broader community; and
d. all researchers' rights are affirmed to carry out appropriately approved research investigations.

(13) The University, via the processes set out in the Governance Document Framework, is responsible for establishing and maintaining an institutional research governance structure, which includes but is not limited to:

a. legal and regulatory compliance;
b. research quality, culture and practice;
c. protection of researchers and participants;
d. protection of animals;
e. privacy and confidentiality;
f. safety of research;
g. financial resources and probity; and
h. risk management.

Responsibilities of the Deputy Vice-Chancellor Research and Community Connection

(14) The Deputy Vice-Chancellor Research and Community Connection will ensure the ongoing establishment, resourcing and operation of:

a. the HREC to review, approve and monitor all non-medical human research and health and medical human research; and
b. the AEC to review, approve and monitor all research and teaching activities involving animals as defined by the Animal Protection Act 2018.

(15) The DVCRI will facilitate the University's support of and engagement with the DRIBC, administered by the Menzies School of Health Research, which represents three organisations conducting genetic research in the region, namely:

a. Charles Darwin University;
b. Menzies School of Health Research; and
c. the Northern Territory Government.

(16) The DRIBC is constituted and administered in accordance with the Gene Technology Act 2000 (Cth) and reports to the Commonwealth Government Office of the Gene Technology Regulator, as well as to the heads of the supported organisations.

(17) The DVCRI will ensure that suitable arrangements are made for induction, formal training, and continuing education of University researchers in research ethics and that these responsibilities are regularly monitored and evaluated and reported upon as prescribed below.

Responsibilities of heads of faculties and institutes:

(18) Faculty Pro Vice-Chancellors, Associate Deans Research, and heads of research institutes will:

a. ensure researchers within their units are adequately trained, qualified, or supervised to perform their research;
b. support researchers within their units to perform ethics committee roles and/or provide peer review mentoring and support to ethics applications; and
c. monitor the research undertaken in coursework courses to ensure it is no more than negligible risk, according to the National Statement and follows the procedures of Program Ethics Approval. In exceptional circumstances, the research supervisor can submit an individual ethics application during the planning stage for a student project that is greater than negligible risk or involves one of the special categories of research participants (cognitive impairment, mental illness, First Nations, dependent on medical care, illegal activity, pregnancy/foetus, dependent/unequal status). These ethics submissions would need to be reviewed by the full HREC.

Responsibilities of researchers

(19) Researchers must comply with this policy and embed good ethics practice in all aspects of their work before the commencement of research and regularly evaluate and make adjustments as needed during the conduct and supervision of approved research.

(20) All researchers must:

a. consult all relevant University resources in preparing their application, make applications for ethics approval using the University's approved documents, and supply all relevant information required;
b. not conduct research without the required research ethics approval;
c. not intentionally or recklessly provide incorrect or misleading information in an application for research ethics approval;
d. disclose conflicts of interest to ethics committees and, where appropriate, to potential participants;
e. conduct research in accordance with the research protocol and conditions as approved by the relevant ethics committee;

f. obtain additional ethical approval(s) from the relevant committee when required;
g. maintain records of all ethics approvals;
h. comply with all of the conditions of approval as stated in correspondence from the relevant committee;
i. report any serious adverse events to the Ethics team within 72 hours of the event occurring;
j. ensure they have adequate research ethics experience, qualifications and competency;
k. undertake education and training in ethical research, as appropriate or as required by the University; and
l. act as principal investigator for HDR projects they superbie and provide guidance, supervision, and mentorship to their HDR students.

Human Research Ethics

(21) The National Statement is used to inform the design, ethical review and conduct of human research that is funded by, or takes place under the auspices of, the University.

(22) All University researchers and research students, including honorary appointees or visitors, must obtain approval through the HREC for research involving human subjects or their data, once the methodology of the research project, the oversight of its conduct, and the requirements of any third parties are fully understood and agreed.

(23) The ethics proposal must:

a. explain how the research will be conducted ethically and with minimal risks to participants; and
b. use the applicable resources and forms published on the University's website.

(24) The ethics proposal must identify all potential risks with the research and provide a detailed management process for each risk.

(25) Research students of the University undertaking their research project through the Menzies School of Health Research must obtain approval from the Northern Territory Department of Health and Menzies HREC regardless of where that research will take place or where the researcher is based. Reciprocal approval should also be sought through the University's HREC.

(26) The University is committed to minimising risk to participants, researchers, third parties and the University itself whilst ensuring review processes are efficient, constructive and proportional to the sensitivities and risks associated with individual projects.

(27) Human research ethics review processes are undertaken through either the Executive Review pathway or the Committee Review pathway depending on the nature of the project and its intended participants, as described in the Human Research Ethics Committee Terms of Reference.

First Nations Research

(28) All research involving and potentially impacting First Nations peoples requires HREC review and approval before the project commences.

(29) Research involving and potentially impacting First Nations peoples must be informed by the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research, and/or the Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders 2018, published by the NHMRC.

(30) When seeking HREC approval for research involving First Nations peoples, researchers must demonstrate that they have sought and received approval from relevant First Nations cultural authorities.

Exemptions

(31) Some research projects that use existing, non-identifiable data in the public domain and which are of negligible risk may be eligible for exemption as per Chapter 5.1.15 and 5.1.18 of the National Statement. An application for ethics exemption must be submitted to the Ethics team. An ethics exemption letter will be provided if applicable.

Reciprocal applications

(32) The University is committed to recognising approvals by other properly registered ethics committees by means of reciprocal approvals.

(33) Projects which already have ethical clearance approval from another institution's ethics committee but which involve University staff or students as investigators must seek reciprocal approval from the HREC.

Suspension of research or withdrawal of approval

(34) Where the HREC has reason to believe that continuance of a research project will compromise participants' welfare or if the conditions of ethics approval for the project (including reporting requirements) are not being adhered to, the committee or HREC Chair will immediately seek to establish whether ethics approval and/or authorisation for the project should be suspended or withdrawn.

Animal Ethics

(35) The Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition 2013 (the Code) promotes the ethical, humane and responsible care and use of animals used for scientific purposes. It provides guidance for investigators, institutions, animals ethics committees, animal carers and all those involved in the care and use of animals for scientific purposes.

(36) Animal welfare and ethics at the University is administered by the Animal Welfare Officer (AWO) and the Animal Ethics Committee (AEC) in accordance to the NT Animal Protection Act 2018 and Animal Protection Regulations 2022 and the Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition 2013.

(37) Under the Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition 2013, scientific purposes includes observational use of animals, including but not limited to camera trapping, call playback, and observation via drone.

(38) All University researchers and research students, including honorary appointees, visitors, and teachers using animals in coursework, must obtain approval through the AEC for all scientific purposes involving animals. Research or teaching must not commence until approval is obtained.

a. University staff who are the principal investigator on a project, research students, and other persons using University animals or University animal holding facilities, must obtain AEC approval through the University's AEC and must conduct the project under the University's scientific use of animals licence.
b. The Deputy Vice-Chancellor Research and Community Connection or Director Research may allow an alternative approvals process in special circumstances.
c. Where University personnel work on collaborative projects and are named in an application to another AEC, the CDU AEC must be notified and provided with a copy of the AEC approval and project application. Under these circumstances, an inter-institutional project agreement may be required and must be enacted prior to work commencing.
d. Honorary and adjunct appointees cannot be a principal investigator under the University's scientific use of animals licence.

(39) The ethics proposal must:

a. explain how the research will be conducted ethically, with the minimum impact to animals,and show due consideration for the Three Rs;
b. use resources and approved documents published on the University's website; and
c. comply with the AEC's procedures and guides for monitoring and managing approved research.

(40) The University's animal facilities include holding, experimental, transportation and breeding facilities. The AEC carries out annual inspections of University animal facilities.

(41) The Animal Protection Act 2018 requires that any suspected contraventions of the Act are reported within 7 days. It is an offence under the Act not to do so. Any person who suspects a non-compliance or breach has occurred must notify the Animal Welfare Officer and the AEC immediately to allow reporting within 7 days if required. Non-compliances or breaches that require reporting include contraventions of the:

a. Animal Protection Act 2018;
b. Australian Code for the Care and Use of Animals for Scientific Purposes 8th edition 2013; and
c. AEC project approval or approval conditions.

Breaches of the Code

(42) Failure to comply with this policy could lead to a breach of the Australian Code for the Responsible Conduct of Research, 2018 (the Code).

(43) Breaches of the Code that are related to research ethics will be managed in accordance with the Responsible Conduct of Research Policy and the Responsible Conduct of Research Procedure.

Monitoring and Support

(44) The DVCRI will monitor internal and external compliance with this policy and provide annual reports on compliance both to the Research Committee of the Academic Board and the Audit, Risk and Compliance Committee.

Section 5 - Non-compliance

(45) 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.

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

(47) 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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Effective Date	29th October 2024
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Responsible Executive	Steve Rogers Deputy Vice-Chancellor Research and Community Connection +61 8 89466890
Implementation Officer	Steve Rogers Deputy Vice-Chancellor Research and Community Connection +61 8 89466890
Enquiries Contact	Steve Rogers Deputy Vice-Chancellor Research and Community Connection +61 8 89466890 Research and Innovation

Glossary Terms and Definitions

"Animal" - A live, non-human organism in a category defined as an animal by the Animal Protection Act 2018 (NT) or the Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition 2013.

"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.

"cultural authority" - A cultural authority may include representative organisations such as Traditional Owners and native title corporations and/or those who exercise cultural authority on behalf of a nation or people, such as Elders and other knowledge holders