

Research Ethics Policy

1. PREAMBLE

- 1.1. Charles Darwin University (CDU) promotes and fosters excellence and innovation in research at or above world standard. The University is also committed to research that is conducted responsibly, ethically and with integrity, and that complies with relevant codes and legislation.

2. PURPOSE

- 2.1. The purpose of this policy is to:
- outline the University's policy on human research ethics, animal research ethics, and institutional biosafety;
 - 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;
 - 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;
 - inform the University community of institutional responsibilities regarding ethics; and
 - articulate the responsibilities of those involved in ethical reviews and related protocols.

3. SCOPE

- 3.1. This policy applies to:
- 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);
 - 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;
 - all students of the University who engage in research and/or research related activities while enrolled at the University; and
 - the ethics committees of the University, including the Human Research Ethics Committee (CDU-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.
- 3.2. This policy does not apply to staff employed by Menzies unless they are engaged in research under the auspices of CDU, or unless they are supervising a Higher Degree by Research (HDR) candidate enrolled at CDU. Staff employed by the Menzies must follow the relevant research ethics policies and processes of that institution.

4. POLICY

- 4.1. 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.



- 4.2. The Code states that the primary responsibility for ensuring the integrity of research lies with individual researchers and the University.
- 4.3. The conduct of research involving the participation of humans must comply with the provisions of the [National Statement on Ethical Conduct in Human Research 2007 \(Updated 2018\)](#) (the National Statement).
- 4.4. 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 2013](#) and other legislative requirements of the states and territories in which the research takes place.
- 4.5. The University must comply with the [Gene Technology Act 2000 \(Cth\)](#) and associated regulations.
- 4.6. 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 more stringent standard.

Responsibilities of the University

- 4.7. 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, researchers, the University and the broader community; and
 - d. all researchers' rights are affirmed to carry out appropriately approved research investigations.
- 4.8. The University, via the processes set out in the CDU [Policy 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. privacy and confidentiality;
 - e. safety of research;
 - f. financial resources and probity; and
 - g. risk management.

Pro Vice-Chancellor (Research and Innovation)

- 4.9. The Pro Vice-Chancellor (Research and Innovation) (PVC (RI)) will ensure the ongoing establishment, resourcing and operation of:
 - a. the CDU-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 Welfare Act 1999](#).
- 4.10. The PVC (RI) 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.

4.11. 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.

4.12. The PVC (RI) 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 Colleges and Institutes:

4.13. Heads of Colleges and Research Institutes will:

- a. ensure researchers within their units are adequately trained, qualified, or supervised to perform their research; and
- b. support researchers within their units to perform ethics committee roles and/or provide peer review mentoring and support to ethics applications.

Responsibilities of Researchers

4.14. Researchers must comply with this Policy and embed good ethics practice in all aspects of their work before the commencement of research and during the conduct and supervision of approved research.

4.15. 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 and maintain evidence of such approval;
- g. comply with all of the conditions of approval as stated in correspondence from the relevant committee;
- h. ensure they have adequate research ethics experience, qualifications and competency; and
- i. undertake education and training in ethical research, as appropriate or as required by the University.

Human Research Ethics

4.16. 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.

4.17. All CDU researchers and research students, including honorary appointees or visitors, must obtain approval through the CDU-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.

4.18. The ethics proposal must explain how the research will be conducted ethically and with minimal risks to participants, using information and documents made available by the Office of Research and Innovation provided on the University's website.



- 4.19. The ethics proposal must identify all potential risks with the research and provide a detailed management process for each risk.
- 4.20. CDU research students undertaking their research project through the Menzies School of Health Research must obtain approval from the Northern Territory Department of Health and TEHREC regardless of where that research will take place or where the researcher is based (mandatory review).
- 4.21. 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.
- 4.22. 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.

First Nations Research

- 4.23. All research involving and potentially impacting First Nations peoples requires CDU-HREC review and approval before the project commences.
- 4.24. Research involving and potentially impacting First Nations peoples must be informed by the [Code of Ethics for Aboriginal and Torres Strait Islander Research](#), published by AIATSIS, 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.
- 4.25. When seeking CDU-HREC approval for research involving First Nations peoples, researchers must demonstrate that they have sought and received approval from relevant First Nations cultural authorities. 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.

Exemptions

- 4.26. 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 of the National Statement. A letter of exemption can also be sought from the CDU-HREC where required.

Reciprocal Applications

- 4.27. CDU is committed to recognising approvals by other properly registered ethics committees by means of reciprocal approvals.
- 4.28. Projects which already have ethical clearance approval from another institution's ethics committee but which involve CDU staff or students as investigators must seek reciprocal approval from the CDU-HREC.

Animal Research Ethics

- 4.29. The Australian Code for the Care and Use of Animals for Scientific Purposes 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.
- 4.30. Animal welfare and ethics at CDU is administered by the Animal Welfare Officer (AWO) and the Animal Ethics Committee (AEC) in accordance to the NT Animal Welfare Act and Regulations and the [Australian Code for the Care and Use of Animals for Scientific Purposes 2013](#).
- 4.31. All CDU researchers and research students, including honorary appointees or visitors, must obtain approval through the AEC for all research or teaching involving animals as defined by the [Animal Welfare Act 1999](#). Research or teaching must not commence until approval is obtained.
- 4.32. The ethics proposal must explain how the research will be conducted ethically and with minimal risks to participants, using information and documents made available by the Office of Research and Innovation

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provided on the University’s website. The proposal must comply with the AEC’s procedures and guides for monitoring and managing approved research.

4.33. The University’s animal facilities include holding, experimental, transportation and breeding facilities. The AEC carries out annual inspections of University animal facilities.

Breaches of the Code

4.34. Failure to comply with this Policy could lead to a breach of the Code.

4.35. 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 Procedures.

Monitoring and Support

4.36. The PVC (RI) 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 University’s Audit and Risk Committee.

5. NON COMPLIANCE

5.1. 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.

5.2. 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](#).

RELATED AND SUPPORTING DOCUMENTS

Legislation	Charles Darwin University Act 2003 Animal Welfare Act 1999 Gene Technology Act 2000 (Cth) Australian Code for the Responsible Conduct of Research 2018 National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) Australian Code for the Care and Use of Animals for Scientific Purposes 2013 AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders 2018
Policy	Charles Darwin University Human Research Ethics Committee Terms of Reference Charles Darwin University Animal Ethics Committee Terms of Reference Responsible Conduct of Research Policy Policy Framework
Procedures	Responsible Conduct of Research Procedures
Definitions	CDU Glossary

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GOVERNANCE

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Implementation Officer	Pro Vice-Chancellor, Research and Innovation	
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1.01	8 Nov 2021	Governance	<ul style="list-style-type: none">Admin changes to reflect correct hierarchy and first nations references.