

Research Ethics Procedure

Version 5 – Approved 21 March 2025

Contents

Purpose.....	1
Applicable governance instruments.....	1
Procedure	2
1. General matters.....	2
2. Conflicts of interest	3
3. Peer review.....	3
4. Animal ethics	3
5. Research involving Biological Agents and Genetically Modified Organisms (GMOs)	4
6. Human ethics.....	4
7. Research involving Aboriginal and Torres Strait Islander peoples.....	5
8. Management of research data	6
9. Privacy	6
10. Research ethics and breaches of the Code	6
Related procedures	6
Versions	7
Definitions	7

Purpose

This procedure establishes the framework for research ethics to ensure that all University research activities are conducted ethically and conform to current ethical guidelines.

Applicable governance instruments

Instrument	Section	Principles
<i>Research Policy</i>	2 Responsible Conduct of Research	2.1-2.4
<i>Compliance Policy</i>	2 Conflicts of Interest	2.1
<i>Data and Information Governance Policy</i>	4 Data and Information Management	4.4
<i>Australian Code for the Care and Use of Animals for Scientific Purposes</i> (8th Edition, 2013) <i>Australian Code for the Responsible Conduct of Research</i> 2018 <i>Animal Welfare Act 1993</i> (Tas) <i>Veterinary Surgeons Act 1987</i> (Tas)		

Definitions and acronyms can be found at: <https://www.utas.edu.au/policy/policy-definitions>

Related policy and procedures can be found at: <https://www.utas.edu.au/policy>

<i>Veterinary Surgeons Regulations 2022 (Tas)</i> <i>National Statement on Ethical Conduct in Human Research (2007, updated 2023)</i> <i>Guidelines approved under Section 95 and 95A of the Privacy Act 1988 (Cth)</i> <i>Guardianship Administration Act 1995 Tas (updated 2024)</i> <i>Personal Information Protection Act 2004 (Tas)</i> <i>Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)</i> <i>Guidelines for Ethical Research in Australian Indigenous Studies (2012)</i> <i>Therapeutic Goods Act 1989 (Cth)</i> <i>Note for Guidance on Good Clinical Practices (CPMP/ICH/135/95)</i> <i>Research Involving Human Embryos Act 2002 (Cth)</i> <i>Human Embryonic Research Regulation Act 2003 (Tas)</i> <i>Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (Tas)</i> <i>Prohibition of Human Cloning for Reproduction Act 2008 (Cth)</i> <i>Human Tissue Act 1985 (Tas)</i>		
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Procedure

1. General matters

1.1. The Research Division will:

- a) establish and maintain ethics committees to review the ethical acceptability of research conducted at the University or by University researchers, external partners and external applicants.
- b) provide induction, training, and continuing education resources to University researchers in research ethics.

1.2. Heads of Academic Units will:

- a) ensure researchers are adequately trained, qualified, or supervised to perform their research;
- b) support researchers to serve on ethics committees;
- c) provide peer review mentoring and support to ethics applications;
- d) implement quality assurance mechanisms within their academic unit to support researcher compliance with ethics approval terms and reporting requirements; and

- e) ensure research facilities within their Academic Unit/School are compliant with relevant legislative and regulatory requirements to perform ethical research.

1.3. University researchers will:

- a) ensure they are adequately trained and qualified, or supervised, to undertake the activities related to their research;
- b) obtain ethical approval from the relevant committee when required and maintain evidence of such approval, and
- c) not commence the research or teaching activities until ethical approval is obtained;
- d) conduct research in accordance with the research application approved by the relevant ethics committee as stated on the relevant ethical approval letter.

1.4. University chief investigators have primary responsibility for submitting contemporary quality applications for ethical approval.

1.5. Applications for ethical approval will be lodged through the University's online system. The [Ethics Review Manager \(ERM\) until the 27th June 2025 and the Research Ethics Platform - Integrity IQ \(IIQ\)](#) from the 28th of July 2025. No applications will be submitted online between 27th of June to 28th of July 2025.

1.6. University ethics committees do not take responsibility for governance of research, including legal and regulatory compliance, research culture and practice, protection of participants, safety and quality of research, privacy and confidentiality, financial probity, risk management and monitoring arrangements.

2. Conflicts of interest

- 2.1. Researchers and University Community members will disclose and manage any perceived, potential or actual conflicts of interest in accordance with the conflict of interest principles in the *Compliance Policy*.
- 2.2. University researchers will disclose any perceived, potential or actual conflicts of interest to ethics committees and, where appropriate, to potential participants.

3. Peer review

- 3.1. University researchers will undertake a peer review process prior to submission of an application for ethical approval to ensure quality applications are submitted for research ethics approval as per the [Peer Review Procedure](#).

4. Animal ethics

- 4.1. The University and its researchers will comply with relevant legislation, guidelines and codes relating to ethical practices in research or teaching involving animals including the *Australian Code for the Care and Use of Animals for Scientific Purposes* (8th Edition, 2013) and the *Animal Welfare Act 1993* (Tas).
- 4.2. The Research Division will operate the University of Tasmania Animal Ethics Committee (AEC) to approve, monitor and report on teaching and research activities involving animals.
- 4.3. Research and teaching activities involving animals must be approved by the AEC prior to the commencement of the activity, including the observation, acquisition, transport, breeding, housing and husbandry of the animals.

- 4.4. University of Tasmania Animal Facilities must be registered with the AEC (see [Registration of Animal Facilities](#)) including holding, experimental, transportation and breeding facilities. The AEC carries out facility inspections of University animal facilities every three years (or earlier if the facility has a modification since last inspection).
- 4.5. University researchers conducting research or teaching involving animals will submit an application for ethical approval that:
 - a) Clearly demonstrates that the potential benefits of the research or teaching activity outweigh the impact on animals.
 - b) Clearly demonstrates the application of the 3Rs (Replacement, Reduction, Refinement) in the project in accordance with the *Australian Code for the Care and Use of Animals for Scientific Purposes*.
 - c) Confirms that all researchers and animal carers have appropriate training and experience.
 - d) Ensures adherence to relevant Commonwealth and State/Territory legislation on animal use.
 - e) Establishes processes for the maintenance of accurate records on animal use, welfare assessments, and procedural outcomes.

Once the application is approved, University researchers will:

- a) Establish processes and report unexpected adverse events to the AEC.
 - b) Provide annual progress reports to the AEC and a final report when the project finished.
 - c) Comply with the University's *Veterinary Services Procedure*.
- 4.6. For research undertaken interstate, or at other institutions, University researchers will obtain approval from other AECs where required or appropriate and will follow the requirements of the external AEC.
- 4.7. For research undertaken overseas and lead by the University, researchers will obtain approval from overseas AECs or equivalent bodies where required or appropriate. In such circumstances University researchers must also obtain approval from the University AEC. The University AEC may accept approval granted by a local AEC if the project outcomes and animal welfare considerations meet the requirement of *Australian Code for the Care and Use of Animals for Scientific Purposes*.
- 4.8. University researchers who engage in field work are responsible for obtaining any required permissions from other authorities such as Department of Natural Resources and Environment Tasmania (NRE), access to third party premises, in addition to AEC approval.

5. Research involving Biological Agents and Genetically Modified Organisms (GMOs)

- 5.1. The University and its researchers will work safely and comply with relevant legislation and regulations relating to research or teaching activities involving gene technology, genetically modified organisms, and hazardous microorganisms and microbiological agents.
- 5.2. Researchers conducting activities relating to Biosafety, Biosecurity or Gene Technology are responsible to ensure all approvals and [University requirements](#) are in place before commencing the activity.

6. Human ethics

- 6.1. The University and its researchers will comply with relevant national guidelines, legislation, and codes relating to ethical practices in human research including the *National Statement on Ethical Conduct in Human Research*.

- 6.2. The Research Division, on behalf of the University of Tasmania, will operate a human research ethics committee or committees (**HREC**) to approve and monitor health and medical human research, and all non-medical human research.
- 6.3. University researchers conducting human research must either:
 - a) Seek an exemption from ethics review on the basis that the project meets the criteria defined by *National Statement on Ethical Conduct in Human Research*.
 - b) Submit an application for ethical approval.
- 6.4. In submitting an application an application for ethics approval, University researchers must:
 - a) Ensure the level of risk, Lower Risk or Higher Risk Research, as defined by *National Statement on Ethical Conduct in Human Research* is assessed and identified? when applying for ethics.
 - b) Ensure that the research aligns with the ethical principles of respect of human dignity, research merit and integrity, justice and beneficence.
 - c) Conduct a risk assessment to identify potential risk to participants, researches and others involved in research.
 - d) Provide detailed information on how informed consent will be obtained, and confidentiality maintained, from their participants.
 - e) Outline processes for collecting, storing and managing data according to the University policies and procedures for data management.
 - f) Ensure compliance with all applicable laws and regulations.
 - g) Outline plans for ongoing monitoring throughout the duration of the project.

Once the application is approved, University researchers will:

- a) Establish process and ensure reporting of any deviation to the project protocol.
 - b) Provide annual progress reports to the HREC and final report when the project finished.
- 6.5. For research undertaken outside Tasmania (interstate or overseas), or at other institutions, University researchers will obtain approval from other HRECs (or equivalent bodies if overseas) as required or appropriate. If University researchers are leading the project, then University researchers must apply for University HREC approval of the proposed study and must also obtain approval from the interstate/overseas HREC in accordance with the requirements specified by that HREC.
- 6.6. Researchers are responsible for obtaining University Research Governance approvals for clinical trial projects in accordance with the *Clinical Trial Procedure*.
- 6.7. The HREC may seek indemnity from the sponsor of a clinical trial as a condition for review.

7. Research involving Aboriginal and Torres Strait Islander peoples

- 7.1. University researchers conducting research involving Aboriginal and Torres Strait Islander peoples, their culture or land will conduct their research in accordance with relevant legislation, guides and codes and follow the University's [Best Practice in Aboriginal and Torres Strait Islander Research Ethics](#) Framework.

8. Management of research data

- 8.1. University researchers will ensure that all research data, including data collected from human participants, is managed in accordance with the [Research Data Management Procedure](#) *Research Data Management Procedure*.

9. Privacy

- 9.1. University researchers will ensure that the collection, use and disclosure of any personal, health or sensitive information collected during the course of their research activities is in accordance with the [Data and Information Governance Policy](#) relevant privacy legislation and the University's Privacy Statements.
- 9.2. University HRECs consider the privacy implications of each human research ethics application, however HRECs do not provide legal advice.

10. Research ethics and breaches of the Code

- 10.1. Breaches of the *Australian Code for Responsible Conduct of Research* (Code) that are related to research ethics include, but are not limited to:
- a) conducting research without ethics approval as required by the *National Statement on Ethical Conduct in Human Research* and the *Australian Code for the Care and Use of Animals for Scientific Purposes*;
 - b) failing to provide progress reports;
 - c) failing to conduct research as approved by an appropriate ethics review body;
 - d) not informing an ethics committee of matters relevant to an existing approval; and
 - e) intentionally or recklessly providing incorrect or misleading information in an application for approval.
- 10.2. Concerns and complaints about potential breaches of the Code will be managed in accordance with the [Research Integrity Complaints Procedure](#).
- 10.3. Other compliance breaches will be managed through other University procedures as relevant, such as the *Behaviour Procedure*, *Data Breach Procedure* and *Conflicts of Interest and Gifts and Benefits Declarations Procedure*.

Related procedures

Veterinary Services Procedure

Peer Review Procedure

Research Data Management Procedure

Data Breach Procedure

Behaviour Procedure

Research Integrity Complaints Procedure

Versions

Versions of this procedure and the details of their approval are as per the following table:

Version	Action	Approved by	Business Owner/s	Approval Date
5	Approved	Deputy Vice-Chancellor (Research)	Executive Director Research Operations	21 March 2025
4	Approved	Deputy Vice-Chancellor (Research)	Executive Director Research Operations	26 March 2024
3	Approved	Deputy Vice-Chancellor (Research)	Executive Director Research Operations	5 April 2023
2	Approved	Deputy Vice-Chancellor (Research)	Executive Director Research Operations	14 April 2022
1	Approved	Deputy Vice-Chancellor (Research)	Executive Director Research Operations	20 Nov 2020

* Currency of procedures is confirmed annually. For the details of when this procedure was last confirmed as current, visit the [version history page](#).

Definitions

[Animal](#) | [Animal Ethics Committee](#) | [Animal facility](#) | [Human research](#) | [Human Research Ethics Committee](#)