

## 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 .....	5
9. Privacy .....	5
10. Research ethics and breaches of the Code.....	5
Related procedures .....	6
Versions .....	6
Definitions .....	6

## 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 2018</i> <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>

<p><i>Veterinary Surgeons Regulations 2012 (Tas)</i></p> <p><i>National Statement on Ethical Conduct in Human Research (2007, updated 2018)</i></p> <p>Guidelines approved under Section 95 and 95A of the Privacy Act 1988 (Cth)</p> <p><i>Personal Information Protection Act 2004 (Tas)</i></p> <p><i>Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)</i></p> <p><i>Guidelines for Ethical Research in Australian Indigenous Studies (2012)</i></p> <p><i>Therapeutic Goods Act 1989 (Cth)</i></p> <p>Note for Guidance on Good Clinical Practices (CPMP/ICH/135/95)</p> <p><i>Research Involving Human Embryos Act 2002 (Cth)</i></p> <p><i>Human Embryonic Research Regulation Act 2003 (Tas)</i></p> <p><i>Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (Tas)</i></p> <p><i>Prohibition of Human Cloning for Reproduction Act 2008 (Cth)</i></p> <p><i>Human Tissue Act 1985 (Tas)</i></p>		
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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, and
- 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 perform ethics committee positions
- 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) conduct research in accordance with the research protocol approved by the relevant ethics committee;
  - c) obtain ethical approval from the relevant committee when required and maintain evidence of such approval, and
  - d) comply with the conditions of approval 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 [Ethics Review Manager \(ERM\) online system](#).
- 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. This includes holding, experimental, transportation and breeding facilities. The AEC carries out annual inspections of University animal facilities.
- 4.5. University researchers conducting research or teaching involving animals will:

- a) submit applications for ethical approval in accordance with the [procedures or guides specified by the AEC](#);
  - b) not commence the research or teaching activities until ethical approval is obtained;
  - c) comply with the AEC's procedures and guides for monitoring and managing approved research, and
  - d) 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 animal ethics committees where required or appropriate. In such circumstances University researchers must seek approval from the AEC in accordance with the procedures or guides specified by the AEC.
- 4.7. For research undertaken overseas, University researchers will obtain approval from overseas ethics committees or equivalent bodies where required or appropriate. In such circumstances University researchers must also obtain approval from the University AEC in accordance with the procedures or guides specified by the AEC.
- 4.8. University researchers who engage in field work will gain 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. This includes the *Gene Technology Act 2000* (Cth), the *Biosecurity Act 2015* (Cth) and the *Biosecurity Act 2019* (Tas). Researchers conducting activities involving gene technology or genetically modified organisms will apply for and gain approval from the University Institutional Biosafety Committee (IBC) before commencement of the activity, in accordance with the [Biosafety, Biosecurity and Gene Technology Operations Framework](#).

## 6. Human ethics

- 6.1. The University and its researchers will comply with relevant legislation, guidelines and codes relating to ethical practices in human research including the *National Statement on Ethical Conduct in Human Research* (2007, updated 2018).
- 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 will:
- a) submit applications for ethical approval in accordance with the [procedures or guides specified by the HREC](#), and not commence the research until approval is obtained, or exemption from HREC review is confirmed, and
  - b) comply with the HREC's procedures and guides for monitoring and managing approved research.
- 6.4. For research undertaken outside Tasmania, or at other institutions, University researchers will obtain approval from other human research ethics committees (or equivalent bodies if overseas) as

required or appropriate. In such circumstances University researchers must also obtain approval from HREC in accordance with the procedures or guides specified by the HREC.

- 6.5. Researchers are responsible for obtaining UTAS Research Governance approvals for clinical trial projects. [Clinical-Trial-Governance](#)
- 6.6. 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*.

## 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 conduct research as approved by an appropriate ethics review body;
  - c) not informing an ethics committee of matters relevant to an existing approval, and
  - d) 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:
  - a) *Research Integrity Complaints Procedure*, and
  - b) the University's [Risk Framework](#).
- 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

<u>Version</u>	<b>Action</b>	<b>Approved by</b>	<b>Business Owner/s</b>	<b>Approval Date</b>
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

## Definitions

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