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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
4.1 Research Policy	2 Responsible conduct of research	2.1 – 2.4
Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition, 2013) Australian Code for the Responsible Conduct of Research 2018 Animal Welfare Act 1993 (Tas) Veterinary Surgeons Act 1987 (Tas) Veterinary Surgeons Regulations 2012 (Tas) National Statement on Ethical Conduct in Human Research (2007, updated 2018) Guidelines approved under Section 95 and 95A of the Privacy Act 1988 (Cth)		

Personal Information Protection Act 2004 (Tas)

Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities:
Guidelines for researchers and stakeholders (2018)

Guidelines for Ethical Research in Australian Indigenous Studies (2012)

Therapeutic Goods Act 1989 (Cth)

Note for Guidance on Good Clinical Practices (CPMP/ICH/135/95)

Research Involving Human Embryos Act 2002 (Cth)

Human Embryonic Research Regulation Act 2003 (Tas)

Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (Tas)

Prohibition of Human Cloning for Reproduction Act 2008 (Cth)

Human Tissue Act 1985 (Tasmania)

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, formal training, and continuing education to University researchers in research ethics.

1.2 Heads of Schools will:

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

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 The University and its researchers will disclose and manage conflicts of interest in accordance with the Conflict of Interest Procedure.
 - 2.2 University researchers will disclose 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, where appropriate, 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 *Tasmanian Animal Welfare Act 1993*.
 - 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. Research and teaching activities involving animals must be approved by the AEC prior to the commencement of the activity, including the acquisition, transport, breeding, housing and husbandry of the animals.
 - 4.3 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.
 - 4.4 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](#), and not commence the research or teaching until approval is obtained;
 - b comply with the AEC's procedures and guides for monitoring and managing approved research, and

c comply with the University's Veterinary Services Procedure.

4.5 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 ratification from the University AEC in accordance with the procedures or guides specified by the AEC.

4.6 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.

4.7 University researchers who engage in field work will gain any required permissions from other authorities, in addition to AEC approval.

5 Research involving 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)*.

5.2 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 Gene Technology Procedure and 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 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 University HREC](#), and not commence the research until approval is obtained, or exemption from HREC review is confirmed, and

b comply with the University 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 or ratification from a University HREC in accordance with the procedures or guides specified by the University HREC.

6.5 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 Management of Research Data 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](#) and relevant privacy legislation.

9.2 University HRECs consider the privacy implications of each human research ethics application, however HRECs will not provide legal advice.

10 Research ethics and breaches of the Code

10.1 Breaches of the 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 Managing Research Integrity and Potential Breaches of Responsible Research Conduct Procedure, and
- b the University's [Risk Framework](#).

10.3 Potential breaches will be reported through the University's [Legal Compliance Framework](#).

Related Procedures

Veterinary Services Procedure

Peer Review Procedure

Management of Research Data Procedure

Gene Technology Procedure

Conflicts of Interest Procedure

Managing Research Integrity and Potential Breaches of Responsible Research Conduct Procedure

Versioning

<i>Versions</i>	<i>Item No</i>	<i>Action</i>	<i>Approval Authority</i>	<i>Responsible Officer/s</i>	<i>Approval Date</i>
1	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](#)