

University of Tasmania Human Research Ethics Committee

Terms of Reference

Responsible Officer	Manager – Research Ethics Unit
Approved by	Deputy Vice-Chancellor (Research)
Approved and commenced	11 April 2022
Amendment incorporated	6 November 2023
Amendment Approved	7 November 2023
Review by	November 2025
Relevant Legislation, Ordinance, Rule and/or Governance Level Principle	<ul style="list-style-type: none"> • Research Policy • Research Ethics Procedure • NHMRC National Statement on Ethical Conduct in Human Research 2007 (updated 2013)
Responsible Organisational Unit	Research Ethics Unit

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1. Establishment

- 1.1. The University of Tasmania (“the University”) establishes the University of Tasmania Human Research Ethics Committee (the “HREC”) under Section 6.2 of the Research Ethics Procedure.
- 1.2. The HREC is established and functions in accordance with the principles outlined in the *National Statement on Ethical Conduct in Human Research* (“the National Statement”) as published by the National Health and Medical Research Council and updated from time to time.

2. Responsibilities and Functions

- 2.1. The HREC will review proposed research with or about people, or their data, or tissue (“human research”), which is undertaken under the auspices of the University, and either approve or not approve the commencement of such research as the case may be.
- 2.2. The HREC will ensure it is sufficiently informed on all aspects of the proposed human research before deciding whether a proposal is approved or not approved.
- 2.3. The HREC is responsible for ensuring that human research:
 - 2.3.1. is designed in accordance with the *Australian Code for the Responsible Conduct of Research* (“the Code”), *Ethical conduct in research with Aboriginal and Torres Strait Islander peoples: Guidelines for researchers and stakeholders* (“the ATSI Guidelines”) and any other relevant national codes of human research;
 - 2.3.2. meets relevant scholarly or scientific standards (defined as research that has merit in Section 1.1 of the National Statement);
 - 2.3.3. is conducted by persons who the HREC believes are either adequately experienced, qualified or supervised and understand the need to assess risks to their own safety and that of participants;
 - 2.3.4. is conducted in a manner which conforms to any proposal which has been approved by the HREC. Oversight of conduct may be delegated to an independent body (for example, a data safety monitoring board) at the discretion of the HREC.
- 2.4. The HREC will document or accept and implement procedures published by the University or an external source for:
 - 2.4.1. managing conflicts of interest from HREC members;
 - 2.4.2. the role and function of Category F members, as defined in Section 3.3, to support a culture of ethical conduct outside of the application review process;
 - 2.4.3. monitoring human research in a way which is commensurate with the risk, size and complexity of the research;
 - 2.4.4. determining the criteria and review pathways for human research which is no more than low risk, and incorporate the principles outlined in Chapter 5.3 of the National Statement to minimise duplication of ethical review where possible;
 - 2.4.5. managing relevant risks associated with clinical trials;
 - 2.4.6. handling complaints regarding the conduct of human research;

- 2.4.7. the format and presentation of human research proposals for review;
 - 2.4.8. reporting and handling of adverse occurrences to research participants;
 - 2.4.9. ensuring the HREC is accountable for demonstrating fulfilment of the functions of an HREC as defined in Chapter 5.2 of the National Statement;
 - 2.4.10. committee recordkeeping, confidentiality and operational guidelines, and
 - 2.4.11. any other standard operating procedures specifically prescribed by the National Statement.
- 2.5. The HREC will either assume or appropriately delegate any responsibilities within the procedures it documents or accepts.
 - 2.6. The HREC will provide advice and feedback to University staff and students conducting, or proposing to conduct, human research on the requirements of the National Statement, the Code and the ATSI Guidelines, and promote a culture of ethical conduct at the University.
 - 2.7. To enable the HREC to fulfil its roles and perform its functions, it may form or appoint such subcommittees as it considers necessary.
 - 2.8. The HREC will report on its operations to the Deputy Vice-Chancellor (Research) annually.
 - 2.9. The HREC may also accept the responsibilities and functions outlined in Sections 2.1-2.4 for research conducted in Tasmania, where the research strategically aligns with the University of Tasmania and the HREC has the capability, by institutions other than the University on a case-by-case basis.

3.Membership and Meetings

- 3.1. Achieving gender equality and diversity significantly increases the talent pool from which our membership is drawn. Diversity and inclusion are important principles for fostering an inclusive and productive membership in which all individuals can achieve their best and feel valued. The HREC seeks to achieve a 50% gender balance across the membership.
- 3.2. In recognition of the University of Tasmania's support of the meaningful involvement of Indigenous persons in University governance and management, the HREC will include an Aboriginal or Torres Strait Islander representative in one of the categories listed in 3.3.
- 3.3. The HREC will comprise at least 8 members from the following categories:
 - a. a Chairperson with leadership and research experience, whose other responsibilities will not impair the HREC's capacity to carry out its responsibilities;
 - b. at least two lay people of different genders, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
 - c. at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
 - d. at least one person who performs a pastoral care role in a community. This may include Aboriginal elders, individuals involved in social outreach or social work, non-ordained or 'lay' members of a religious community, or individuals who provide or lead social or health programs, such as youth mentoring or drug and alcohol programs, or who perform pastoral care roles in hospitals, schools, universities or other organisations (e.g.

- people that have a support role but are not counsellors).
- e. at least one person qualified to practice law, and
 - f. at least two people with current research experience that is relevant to human research proposals to be considered at the meetings they attend.
- 3.4. The Manager – Research Ethics Unit (“the Manager”) will also appoint at least one member to serve as Deputy Chairperson on such terms and conditions as the Manager determines. Ordinarily, the Deputy Chairperson will also lead and control meetings of the HREC in the absence of the Chairperson.
- 3.5. The Chairperson (s) reports to the Deputy Vice-Chancellor (Research) and receives broad direction from the Manager.
- 3.6. For the purposes of a meeting of the HREC, where possible, no member may fill more than one of the categories listed in 3.3, although members may be selected from a pool of inducted members in each category.
- 3.7. Members of the HREC whom are also employees of the University of Tasmania will ordinarily be academic staff members, and will attend meetings as required and perform the responsibilities listed in Section 6 within the portion of their workload allocated to service functions.
- 3.8. Other members may be added to the HREC at the discretion of the Chairperson or the Manager to ensure sufficient expertise is present to fulfil the responsibilities and functions of the HREC.
- 3.9. Meetings will be held at a frequency determined by the Manager, and may be in-person, or via videoconference.
- 3.10. To achieve the quorum for a meeting of the HREC, the minimum number of members for each category listed in 3.3 must either be present or provide documented comments *in absentia* to be tabled by the chairperson in lieu of physical attendance at a meeting. Such comments will be included in any decisions made by the HREC, and will be considered as attendance by that member to count towards the quorum. For the avoidance of doubt, a quorum consists of 8 persons.
- 1.1. The Manager has the option to participate in the meeting as an observer, without actively engaging in discussions or offering opinions, unless otherwise requested by the HREC members. Attending the meetings will enable the Manager to check for consistency and continuity between different HREC meetings.
- 3.11.

4. Decision making

- 4.1. Decisions at meetings will ordinarily be made following an exchange of views from those members who comprise the minimum membership, whether in full attendance or through the receipt and consideration of written comments in compliance with Section 3.9.
- 4.2. Decisions of the HREC will be made by general agreement, and need not involve unanimity of members’ opinions.
- 4.3. The HREC will document minutes of every meeting which capture details of all decisions

made by the committee, and where necessary include reasons for those decisions.

- 4.4. The HREC will review and endorse reports on the function of the committee as prepared for external regulatory agencies or funding bodies.

5.Appointments

- 5.1. The University of Tasmania, via the Manager, may recruit members for the HREC in such manner and shall appoint them for such periods and on such terms and conditions as it determines. In ordinary circumstances:
 - 5.1.1. open and transparent processes will be adopted for the advertisement of membership opportunities and making appointments of members;
 - 5.1.2. members will be appointed by the Manager for a nominal term of two years, which may be extended by negotiation;
 - 5.1.3. members will be provided with an assurance of legal protection for liabilities which may arise in the course of bona fide conduct of their duties as a member;
 - 5.1.4. members who are absent from three consecutive meetings without approval of the chairperson or Manager may have their HREC membership terminated;
 - 5.1.5. the appointment of any member may be terminated if the chairperson or Manager determines that it is necessary for the proper and effective functioning of the HREC. This includes members who fail to meet appointment criteria (such as continued nonattendance to meetings or lack of contribution at meetings) or who do not adhere to the University Behaviour Procedure;
 - 5.1.6. members may resign their membership by written notice to the Manager and chairperson;
 - 5.1.7. in the short term-term absence of a member, a proxy may be appointed by the Manager in consultation with chairperson as a temporary replacement; and
 - 5.1.8. new members will be provided with an induction and orientation to the functions of the HREC, and offered the opportunity of mentoring from an existing member.

6.Members' Responsibilities

- 6.1. Each member must demonstrate a working knowledge of the National Statement, the Code, ATSI Guidelines and familiarity with other relevant guidelines or legislation.
- 6.2. Each member is responsible for deciding whether a proposal submitted to the HREC meets the requirements of the National Statement and is ethically acceptable.
- 6.3. Each member must:
 - 6.3.1. disclose any actual, perceived and potential conflicts of interest that may affect their unbiased conduct;
 - 6.3.2. protect the confidentiality of the content of applications and deliberations of the HREC;
 - 6.3.3. attend HREC meetings as scheduled. If a meeting cannot be attended, documented comments must be provided in accordance with Section 3.9, and

- 6.3.4. attend continuing education and training programs in research ethics, as required in accordance with the National Statement.
- 6.4. Members who are not staff members of the University may be offered reimbursement of expenses incurred through attendance at meetings up to a maximum value as determined by the Manager.
- 6.5. In addition to the responsibilities listed above, the chairperson (either Chair or Deputy Chair) of the meeting will have the following responsibilities:
 - 6.5.1. ensure that committee decisions are informed by an exchange of views from those members who comprise the minimum membership, whether in full attendance or through the receipt and consideration of written comments;
 - 6.5.2. facilitate the expression of opinion from all members, identify points of agreement and of disagreement, and judge when a sufficient degree of agreement (which need not be unanimous) has been reached to make a decision;
 - 6.5.3. review and approve human research proposals which are no more than low risk if required by a documented procedure in satisfaction of Section 2.4.4, and
 - 6.5.4. seek advice from non-member experts to assist in the review of human research proposals where necessary.

7.Accountability

- 7.1. Under the terms of the University's Legal Compliance Framework, as endorsed by the University's Audit and Risk Committee and updated from time to time, the National Statement is a Tier 2 compliance risk. Accountability for compliance with the National Statement is apportioned as follows, with definitions of each responsibility level outlined in the Legal Compliance Framework:
 - 7.1.1. Compliance Owner: Deputy Vice-Chancellor (Research)
 - 7.1.2. Delegate 1: Executive Director (Research Operations)
 - 7.1.3. Delegate 2: Manager – Research Ethics Unit
 - 7.1.4. Specialist Officer 1: HREC Chairperson(s)
- 7.2. Researchers have responsibility for the ethical design and conduct of research. For the avoidance of doubt, researchers are required to provide evidence of the ethical design and merit of their application in a format determined by the HREC. The measures of accountability by which researchers demonstrate, to institutions and to the HREC, fulfilment of those responsibilities appear in National Statement Chapter 5.1: Institutional responsibilities, Chapter 5.2: Responsibilities of HRECs, other ethical review bodies and researchers, and paragraph 3.3.22, on the monitoring of approved clinical research.
- 7.3. The HREC has responsibility for the ethical review of research. The measures of accountability by which the HREC demonstrates to the University their fulfilment of those responsibilities appear in National Statement Chapter 5.2: Responsibilities of HRECs, other ethical review bodies, and researchers.
- 7.4. The University has responsibility to ensure that ethical review of research occurs in accordance with the principles of the National Statement, and that research is conducted in

compliance with the Code.

- 7.5. In fulfilment of its obligations, the university and its HREC is required to report annually, or upon request, to the NHMRC on the HREC activities for the preceding calendar year (5.8.4). This report is prepared by the REU and must be endorsed by the HREC Chairperson and DVCR.

8. Versioning

These terms of reference shall be reviewed every two years.

	SSHREC	HMHREC
Former Version(s)	<p>Version 1 – Tasmanian Social Science Human Research Ethics Committee; approved 3 May 2016</p> <p>Version 2 – Research Integrity and Ethics Committee; approved 2019. Tasmanian Social Sciences Human Research Ethics Committee; approved 17 June 2019</p>	<p>Version 1 – Research College Board; approved 17 February 2015, Tasmanian Research Integrity and Ethics Committee; approved 7 November 2015, Tasmanian Health and Medical Ethics Committee; approved 7 November 2015</p> <p>Version 2 – Research Integrity and Ethics Committee; approved 2019. Tasmanian Health and Medical Human Research Ethics Committee; approved 26 March 2019</p>
	Version 1 – UTAS HREC Terms of Reference, drafted 7 May 2021 Approved 7 June 2021	
	Version 2 – UTAS HREC Terms of Reference, drafted 16 November 2021 Approved 20 December 2021	
	Version 3 – UTAS HREC Terms of Reference, drafted 7 April 2022 Approved 11 April 2022	
Current Version	Version 4 – UTAS HREC Terms of Reference, drafted 6 November Approved 7 November 2023	