Tasmanian Health and Medical Human Research Ethics Committee (HMHREC) Terms of Reference

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<tr>
<th>Responsible Officer</th>
<th>Executive Officer, Health and Medical Human Research Ethics Committee</th>
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<tr>
<td>Approved by</td>
<td>Deputy Vice Chancellor of Research</td>
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<tr>
<td>Approved and commenced</td>
<td>March 2019</td>
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<tr>
<td>Relevant Legislation, Ordinance, Rule and/or Governance Level Principle</td>
<td>University Research Ethics Policy NHMRC National Statement on Ethical Conduct in Human Research 2007 (updated 2018)</td>
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<td>Responsible Organisational Unit</td>
<td>Research Integrity and Ethics Unit</td>
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1 Establishment

1.1 The Tasmanian Health and Medical Human Research Ethics Committee, to be known as the HMHREC, is a committee of the Human Research Ethics Committee (HREC) Tasmania network.

1.2 The University of Tasmania Research Ethics Policy confers responsibility to the HMHREC for the review, approval and monitoring of all health and medical research involving human participants (including the use of their data or tissue) undertaken by researchers of the University of Tasmania, the Department of Health and Human Services (through agreement) and external researchers.

1.3 The HMHREC acts in accordance with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research 2007 (updated 2018) and has executive authority conferred upon it to fulfil the roles and carry out the functions detailed in these Terms of Reference.

2 The Scope of Responsibility

The HMHREC is responsible for conducting scientific and ethical reviews of:

2.1 Research involving:
   - Physiological, clinical and/or medical interventions
   - The use of human biospecimens
   - Human genetic research
   - Staff, patients or resources in a health provider setting (both public and private)

2.2 Proposals for human research to be undertaken at, or under the auspices of, the University of Tasmania (this applies to all staff, students, visiting fellows/scholars and persons holding discretionary titles of the University of Tasmania)

2.3 Proposals for human research to be undertaken by the Department of Health and Human Services (DHHS) and/or external researchers not affiliated with these organisations.

3 Roles

The roles of the HMHREC are to:

3.1 Ensure that the design and conduct of any human research it reviews is within the scope of its responsibilities and conforms with the National Statement on Ethical Conduct in Human Research 2007 (updated 2018), Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders and other relevant national codes of human research ethics.
3.2 Ensure that the following provisions for clinical trials are adhered to:

- Relevant investigators involved in the conduct or governance of clinical trials are adequately trained, including current certification in Good Clinical Practice
- Non-commercial clinical trials have a monitoring plan to be led by the Chief Investigator and the necessary budgetary provisions for adequate safety monitoring
- Adequate liability insurance in place for investigators and participants
- Any required Therapeutic Goods Administration (TGA) approvals are in place

3.3 Ensure that participants, in any human research that it reviews and approves, are accorded the respect and protection the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) requires

3.4 Facilitate and foster human research that is of benefit to Australian communities

3.5 Ensure that any decision it makes complies with relevant state and federal laws

4 Functions

In fulfilling these roles, the HMHREC will:

4.1 Receive and review proposals for human research projects, to determine whether they meet ethical standards as defined in the National Statement on Ethical Conduct in Human Research 2007 (updated 2018)

4.2 Receive and review proposals for human research projects, to determine that there will be mechanisms to monitor the conduct of the research and that the frequency and type of those mechanisms reflect the degree of risk to participants

4.3 Ensure that it is sufficiently informed on all aspects of a research proposal, including its scientific validity, before deciding whether a proposal is acceptable on ethical grounds and conforms with the National Statement on Ethical Conduct in Human Research 2007 (updated 2018)

4.4 Advise the applicants whether or not the reviewed research proposals meet relevant ethical standards, have or have not been approved and provide reasons for those decisions linked to National Statement on Ethical Conduct in Human Research 2007 (updated 2018) etc.

4.5 Promote adequate ethical review processes in order to eliminate any unnecessary duplication of ethical review of human research a per the National Statement Chapter 5.3.

4.6 Where appropriate, delegate to a subcommittee to assist in the expeditious and effective ethical review of research proposals. The HMHREC will remain responsible and accountable for the activities and recommendations of any subcommittees

4.7 Consider issues referred by the Deputy Vice-Chancellor (Research) (DVCR) of the University of Tasmania and Research Integrity and Ethics Committee (RIEC)

4.8 Where appropriate, provide advice to the DVCR of the University of Tasmania and RIEC, particularly on research policy and procedural issues with ethical implications
Provide a forum in which researcher and participant concerns, regarding ethical issues in research, can be considered and investigated

Promote a deeper understanding of ethical issues related to research through educational activities

5 Membership

5.1 The HMHREC composition will be in accordance with the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) and have at least eight (8) members, namely;

- A Chair, with suitable experience, whose other responsibilities will not impair the HMHREC’s capacity to carry out its obligations under the National Statement on Ethical Conduct in Human Research 2007 (updated 2018),

- At least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work,

- 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,

- At least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion,

- At least one lawyer, where possible one who is not engaged to advise the University of Tasmania,

- At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

5.2 The DVCR of the University of Tasmania, in consultation with the HMHREC Chair, will also appoint, from the HMHREC members, one member to serve as Deputy Chair on such terms and conditions as the DVCR determines

5.3 The University of Tasmania may add other persons to the membership, as is necessary to ensure that the HMHREC has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider

6 Appointment

The University of Tasmania may recruit members for the HMHREC in such manner and shall appoint them for such periods and on such terms and conditions as it determines, however in ordinary circumstances:

5.4 The University of Tasmania will adopt open and transparent processes, including advertising for applications for membership and making appointments of members
5.5 Members will be appointed by the DVCR of the University of Tasmania for a term of two years and eligible for re-appointment for a second and third term. No member may serve more than three successive terms, except with the express approval of the DVCR, in consultation with the HMHREC Chair.

5.6 All recommendations for membership will be provided to the DVCR of the University of Tasmania, who will make the appointments.

5.7 Members will receive a formal notice of appointment that will include an assurance by the institution of legal protection for any liability that may arise in the course of the bona fide conduct of their duties.

5.8 Members who are absent from three successive meetings of the HMHREC without the approval of the Chair will cease to be members.

5.9 Members may resign their membership by written notice to the HMHREC Chair.

5.10 The appointment of any member may be terminated if the HMHREC Chair or DVCR of the University of Tasmania determines that it is necessary for the proper and effective functioning of the HMHREC.

5.11 In the short term-term absence of a committee member, a proxy can be appointed in consultation with HMHREC Chair as a temporary replacement.

7 Members Responsibilities and Entitlements

5.12 A working knowledge of the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) and familiarity of other relevant guidelines and legislation is expected of all members.

5.13 Each member is responsible for deciding whether a proposal submitted to the HMHREC meets the requirements of the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) and is ethically acceptable.

5.14 Each member will be provided with an induction and orientation to the functions of the HMHREC and be offered the opportunity of being mentored by a current HMHREC member.

5.15 Each member has the responsibility to:

- Disclose to the HMHREC any actual and potential conflicts of interest that may affect research and its review as per the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) and the University of Tasmania Conflict of Interest Policy.

- Protect the confidentiality of the content of applications and the deliberations of the Committee received in the exercise of their duties.

- Prepare for and attend HMHREC meetings. If members are unable to attend, comments on agenda items is advisable prior to the meeting to ensure proper and effective functioning of the HMHREC.
Attend continuing education and training programs in research ethics, as required in accordance with the National Statement on Ethical Conduct in Human Research 2007 (updated 2018).

5.16 Members who are not staff members of the University of Tasmania may be offered an honorarium for each attendance at a committee meeting. The value of the honorarium will be determined by the DVCRC of the University of Tasmania.

8 Chair and Deputy Chair Responsibilities

In addition to the responsibilities as members, the HMHREC Chair and Deputy Chair will have the following responsibilities:

5.17 The Chair must not have other responsibilities that will impair the HMHREC’s capacity to carry out its obligations under the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) and carry out the functions set out in these Terms of Reference.

5.18 Ensure that HMHREC 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. To achieve such decisions, the Chair must:

- Actively engage all members
- Elicit their views
- Communicate their responses to other members

8.4 Facilitate the expression of opinion from all members, identify points of agreement and of disagreement, and judge when a sufficient degree of agreement has been reached. The HMHREC endeavors to reach decisions by general agreement, which need not involve unanimity.

8.5 Guide the manner in which the HMHREC communicates with researchers and the decisions about inviting researchers to attend meetings.

8.6 Where the Chair cannot attend meetings, or perform any other function as requested, the Deputy Chair should be capable of fulfilling the responsibilities.

8.7 The Chair may seek advice from experts to help in considering a research proposal. Such experts should be bound by the same confidentiality and conflicts of interest requirements as the HMHREC members.

9 Accountability

9.1 The HMHREC is accountable to the DVCRC of the University of Tasmania and RIEC for the exercise of its functions and the fulfilment of its roles.

9.2 The HMHREC will provide an annual report to the DVCRC of the University of Tasmania and RIEC that contains a summary account of:

- The number of research ethics proposals received, reviewed, approved and rejected.
• Any complaints received from:
  − Researchers about the conduct of the HMHREC
  − Participants, or others, about the conduct of research approved by the HMHREC

• Any changes in membership of the HMHREC

• Any changes in the procedures used for the performance of its functions

• Any changes in staffing levels and personnel who provide administrative support to the HMHREC

• An evaluation of the performance of the HMHREC identifying any factors (including the level of administrative support) that have affected or may affect the integrity and efficiency of the HMHREC

9.3 The HMHREC Chair will review and endorse any reports of activities of the HMHREC, whether to the University of Tasmania, the National Health and Medical Research Council (NHMRC) and the Department of Health and Human Services of Tasmania (DHHS)

9.4 The HMHREC, through the Chair, may at any time bring to the attention of the DVCR of the University of Tasmania or external stakeholders any issues of significant concern that merit prompt consideration and attention

10 Subcommittees

To enable the HMHREC to fulfil its roles and perform its functions, it may appoint such subcommittees as it considers necessary.

9.5 Ensure that it is sufficiently informed on all aspects of a research proposal, including its scientific validity, before deciding whether a proposal is both acceptable on ethical grounds and conforms with the National Statement through review by its subcommittee, the Tasmanian Scientific Research Advisory Committee (TSRAC), which operates under a separate Terms of Reference but reports to the HMHREC through the Chair of TSRAC;

9.6 Establishment of an Executive Committee where required, as determined by the Chair

11 Meetings

9.7 The HMHREC will meet each month. The dates of meetings and submission closing dates for applications will be published on the University of Tasmania website

9.8 Decisions at meetings will 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

9.9 The HMHREC will endeavor to reach decisions by general agreement, which need not involve unanimity

9.10 The HMHREC will record decisions about approval, amendment or rejection of proposals in
written form, with reasons for those decisions made in accordance with the National Statement on Ethical Conduct in Human Research 2007 (updated 2018)

12 Procedures

The HMHREC shall establish, implement, document and notify the DVCR of the University of Tasmania and RIEC of its working procedures concerning:

- Frequency of meetings
- Role of the Executive Officer
- Attendance at meetings
- Conduct and structure of meetings and deliberations
- Preparation of agendas and minutes
- Timely distribution of papers prior to meetings
- Presentation of applications for ethical review
- Timely consideration and review of applications
- Identifying, declaring and managing conflicts of interest
- Protection of confidentiality of the content of protocols and of committee proceedings
- Communicating, informally and formally, with researchers
- Methods of decision-making
- Prompt notification of decisions
- Record keeping
- Reporting and handling of adverse occurrences
- Receiving and handling of complaints
- Advising institutions of decisions to withdraw ethical approval of a research project
- Attendance of people, other than members or researchers, as observers

13 Versioning

These terms of reference shall be reviewed every two years.

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<tr>
<th>Former Version(s)</th>
<th>Version 1 – Research College Board; approved 17 February 2015, Research Integrity and Ethics Committee; approved 7 November 2015, Tasmanian Health and Medical Ethics Committee; approved 7 November 2015</th>
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<tr>
<td>Current Version</td>
<td>Version 2 – Research Integrity and Ethics Committee; approved 26 March 2019. Tasmanian Health and Medical Human Research Ethics Committee Chair; approved 26 March 2019</td>
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