Tasmanian Health and Medical Human Research Ethics Committee
Terms of Reference
Tasmanian Health and Medical Human Research Ethics Committee

Terms of Reference

Contents

1 Establishment ................................................................................................................................... 2
2 The Scope of Responsibility ............................................................................................................. 2
3 Roles ................................................................................................................................................. 2
4 Functions .......................................................................................................................................... 3
5 Membership ..................................................................................................................................... 4
6 Appointment .................................................................................................................................... 5
7 Members Responsibilities and Entitlements ................................................................................... 5
8 Chair and Deputy Chair Responsibilities and Entitlements ............................................................. 6
9 Accountability .................................................................................................................................. 7
10 Subcommittees .............................................................................................................................. 7
11 Meetings ........................................................................................................................................ 8
12 Procedures ..................................................................................................................................... 8
13 Revision date .................................................................................................................................. 9
1 Establishment

1.1 The Health and Medical HREC is a committee of the HREC (Tasmania) network, to be known as the ‘HREC’. Under the University of Tasmania Research Ethics Policy the HREC has responsibility for the review of all health and medical research projects involving human participation that are undertaken by researchers of the University of Tasmania and through agreement, the Department of Health and Human Services and external researchers who are not affiliated with these organisations.

1.2 The HREC acts by way of delegated authority of the University of Tasmania and has executive authority conferred upon it to fulfil the roles and carry out the functions detailed in these Terms of Reference.

1.3 The Tasmanian Health and Medical HREC will act in accordance with the Terms of Reference as amended from time to time.

2 The Scope of Responsibility
The HREC has been established to conduct scientific and ethical reviews of:

2.1 Research involving the following;

- Invasive physiological clinical and/or medical interventions;
- Research involving the use of human tissue (including blood, reproductive and other tissues)
- Human genetic research and;
- Research involving staff, patients or resources of any hospital in Tasmania (Both public and private)

And;

2.2 Proposals for human research to be undertaken at or under the auspices of the University of Tasmania,

and/or;

2.3 Proposals for human research received by the HREC in the exercise of its function as an accredited HREC for the review of proposals to be undertaken by Department of Health and Human Services and external researcher who are not affiliated with these organisations

3 Roles
The roles of the HREC are to:

3.1 Ensure that the design and conduct of any human research that it reviews within the
scope of its responsibilities conforms with the National Statement on Ethical Conduct in Human Research (National Statement) and Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research AND other relevant national codes of human research ethics and also with the ethical standards to which the University of Tasmania has committed which includes, but is not limited to, the following provisions for clinical trials:

- All 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 TGA approvals are in place.

3.2 Ensure that participants in any human research that the HREC reviews and approves are accorded the respect and protection that is due to them.

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

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

4 Functions
In fulfilling these roles, the HREC will:

4.1 Receive and review proposals for human research projects to determine whether they meet all relevant ethical standards;

4.2 Ensure that it is sufficiently informed on all aspects of a research proposal, including its scientific and statistical 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 to be known as TSRAC, which operates under a separate Terms of Reference but reports to the HREC through the Chair of TSRAC;

4.3 Decide whether participants in all reviewed and approved human research projects will be accorded the protection and respect that is due to them;

4.4 Advise the relevant governance authority and/or Heads of Faculty/School/Department researcher applicants whether or not reviewed research proposals meet relevant ethical standards and have or have not been approved and provide reasons, linked to the National Statement, for those decisions;

4.5 Determine, in relation to each reviewed and approved research project, 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;
4.7 Implement systems adopted by the University of Tasmania to promote the efficient ethical review of multicentre research projects in order to minimise unnecessary duplication of ethical review of human research;

4.8 Have the authority to delegate to a subcommittee any of its powers and functions that are capable of being delegated in order to assist in the expeditious and effective ethical review of research proposals. The HREC will remain responsible and accountable for the activities and recommendations of any subcommittees;

4.9 Consider issues referred by the Deputy Vice- Chancellor (Research) (DVCR) and Research Integrity and Ethics Committee (RIEC) and, where appropriate, provide advice to the DVCR and RIEC, particularly on research policy and procedural issues with ethical implications;

4.10 Provide a forum in which researcher’s and participant’s concerns regarding ethical issues in research can be considered and investigated; and,

4.11 Promote a deeper understanding of ethical issues related to research within the University of Tasmania through educational activities

5 Membership

5.1 The HREC will be constituted in conformity with the National Statement and will have at least eight (8) members, both men and women, namely:

5.1.1 A chairperson, with suitable experience, whose other responsibilities will not impair the HREC’s capacity to carry out its obligations under the National Statement

5.1.2 At least two members who are laypeople, one man and one woman, who have no affiliation with the institution and do not currently engaged in medical scientific, legal or academic work

5.1.3 At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people,

5.1.4 At least one person who performs a pastoral role in a community,

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

5.1.6 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 will also appoint from the appointed members one member to serve as Deputy Chairperson on such terms and conditions and for such a period as the DVCR determines.

5.3 The University of Tasmania may add to the membership such other persons as is necessary to ensure that the HREC 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 HREC in such manner and shall appoint them for such periods and on such terms and conditions as it determines, however in ordinary circumstances:

6.1 The University of Tasmania will adopt open and transparent processes including advertising for applications for membership and making appointments of members.

6.2 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 but no member may serve more than three successive terms, except with the express approval of the DVCR.

6.3 All recommendations for membership will be provided to the DVCR of the University of Tasmanian who will make the appointments.

6.4 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.

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

6.6 Members may resign their membership by written notice to the Chair of the HREC.

6.7 The appointment of any member may be terminated if the Chair of the HREC or DVCR of the University of Tasmania is of the opinion that:

- it is necessary for the proper and effective functioning of the HREC; or
- the person is not a fit and proper person to serve on an HREC.

7 Members Responsibilities and Entitlements

7.1 Each member is responsible for deciding whether, in his or her judgment, a proposal submitted to the HREC meets the requirements of the National Statement and is ethically acceptable. A working knowledge of the National Statement is expected of all members.

7.2 Each member will be provided with an induction and orientation to the functions of the HREC and be offered the opportunity of being assisted by a current HREC member as a mentor.

7.3 Each member is responsible to:

- disclose to the HREC any conflicts of interest that may affect the HRECs review of a research proposal
• protect the confidentiality of information received in the exercise of his or her duties;
• become familiar with the National Statement and other relevant guidelines
• prepare for and attend HREC meetings or, if unavailable, provide opinions on ethical acceptability of research proposals;
• undertake continuing education in human research ethics once every three years as per the National Statement.

7.4 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 from time to time by the DVCR of the University of Tasmania.

8 Chair and Deputy Chair Responsibilities and Entitlements

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

8.1 The Chair must not have other responsibilities that will impair the HREC’s capacity to fulfil its obligations under the National Statement and carry out the functions set out in these Terms of Reference.

8.2 The Chair is responsible to ensure that HREC 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 from some of those members who cannot be present. (NS 5.2.29–30). Achieving such decisions requires that the Chair:
• actively engages all members;
• elicits their views; and
• communicates their responses to other members

8.4 As the HREC endeavours to reach decisions by general agreement, which need not involve unanimity (NS 5.1.31), the Chair will need to facilitate the expression of opinion from all members, identify points of agreement and of disagreement and judge when a sufficient degree of general agreement has been reached.

8.5 The Chair is responsible for guiding the manner in which the HREC communicates with investigators (NS 5.2.13–14, 5.2.22) and the decisions about inviting investigators to attend HREC meetings (NS 5.2.18).

8.6 The Deputy Chair should support the Chair in the performance of, and be capable of fulfilling, the responsibilities of the Chair whenever the Chair cannot attend meetings or perform any other function.
9 Accountability

9.1 The HREC is accountable to the DVCR and Research Integrity and Ethics Committee to be known as the RIEC, of the University of Tasmania for the exercise of its functions and the fulfilment of its roles.

9.2 The HREC will provide copies of the minutes of its meetings to the office of the DVCR or RIEC as requested.

9.3 The HREC will provide an annual report to the DVCR/RIEC that will contain a summary account of:

- the number of research ethics proposals received, reviewed, approved and rejected;
- any complaints received from either researchers about the conduct of the HREC or from participants or others about the conduct of research approved by the HREC;
- any changes in membership of the HREC;
- any changes in the procedures used for the performance of its functions; and
- any changes in staffing levels and personnel who provide administrative support to the HREC.

9.4 The annual report to the DVCR/RIEC will also include an evaluation of the performance of the HREC identifying any factors, including the level of administrative support that have affected or may affect the integrity and efficiency of the HREC’s performance.

9.5 The Chair of the HREC will review and approve any reports of activities of the HREC, whether to the University of Tasmania, to the NHMRC or to the Department of Health and Human Services of Tasmania.

9.6 The HREC, through the Chair, may at any time, bring to the attention of the CEO or delegate any issues of significant concern that merit prompt consideration and attention.

10 Subcommittees

In order to enable the HREC to fulfil its roles and perform its functions, it may appoint such subcommittees as it considers necessary.

10.1 Establishment of ‘executive group’ from time to time to review out of session items and to make decisions as a group, this should only occur for items that are “back to chair” which require additional input within a particular area of expertise. This shall be determined by the Chair as necessary.
11 Meetings

11.1 The HREC will meet each month and will publish the dates of its meetings and submission closing dates for applications.

11.2 Decisions at meetings must be made following an exchange of opinions from each of the members who constitute the minimum membership, whether at a face to face meeting, by teleconference or videoconference or where one of those members is absent, by the receipt and consideration of that member’s views.

11.3 The HREC will endeavour to reach decisions by general agreement, which need not involve unanimity.

11.4 The HREC will record decisions about approval, amendment or rejection of proposals in written or electronic form, with reasons for those decisions linked to the relevant sections, chapters or paragraphs of the National Statement.

12 Procedures

The HREC shall establish, implement, document and notify the DVCR/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 institution(s) or organization(s) of decisions to withdraw ethical approval of a research project
- Attendance of people other than members or researchers as observers.
13 Revision date
These terms of reference shall be reviewed every 2 years.

About this document:

<table>
<thead>
<tr>
<th>Original author (based on ‘Developing Best Practice in Human Ethics Review’ April 2012 Thomson)</th>
<th>Lauren Black, Executive Officer Health and Medical HREC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>1</td>
</tr>
<tr>
<td>Approved by Health and Medical Human Research Ethics Committee</td>
<td>15 December 2015</td>
</tr>
<tr>
<td>Approved by the Research Integrity and Ethics Committee</td>
<td>7 November 2015</td>
</tr>
<tr>
<td>Approved by Research College Board</td>
<td>17 February 2015</td>
</tr>
</tbody>
</table>