Tasmanian Scientific Research Advisory Committee (TSRAC) 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>
</tr>
<tr>
<td>Approved and commenced</td>
<td>March 2019</td>
</tr>
<tr>
<td>Review by</td>
<td>January 2021</td>
</tr>
<tr>
<td>Responsible Organisational Unit</td>
<td>Research Integrity and Ethics Unit</td>
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1 Establishment

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

1.2 The objective of the TSRAC is to review and advise the scientific validity, merit and integrity of health and medical human research applications, prior to their consideration by the HMHREC.

1.3 The TSRAC 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

2.1 The TSRAC is responsible for conducting scientific reviews of health and medical human research proposals and may consider matters including, but not limited to:

- Clinical data
- Rationale and clinical relevance
- Methodology
- Sample size
- Objectives of the proposed study
- Study design (placebo controlled, blinding, etc.)
- Expected outcomes
- Statistical analysis
- Scientific merit
- Relevant expertise of the research team
- Integrity of the proposed study

3 Roles

3.1 The TSRAC may raise ethical concerns with the HMHREC, as deemed appropriate by the members.

3.2 The TSRAC will provide:

- Endorsement and/or advice to the HMHREC of the scientific validity and integrity of the research proposal based on the items above. The TSRAC has the authority to recommend to the HMHREC that proposals be rejected.

- Assistance and feedback to researchers and, where appropriate, a reasonable level of advice to assist researchers to meet the required quality and standards of the National Statement on Ethical Conduct in Human Research 2007 (updated 2018).

3.3 The TSRAC may be required to work with the HMHREC on issues such as procedural development, submissions on matters pertaining to the ethical conduct of research to peak bodies and investigations or responses to complaints, as appropriate and as required.
4 Membership

Committee composition will be determined by the TSRAC and HMHREC Chair’s in consultation with the Research Integrity and Ethics Unit (RIEU) Manager and appropriate stakeholders, thus to permit broad representation/required expertise and efficient functioning.

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<tr>
<th>Role/number of members</th>
<th>Responsible Area (School, Unit, Department)</th>
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<tbody>
<tr>
<td>1 Chair of TSRAC &amp; Deputy Chair of the HMHREC</td>
<td>Appointed by mutual agreement of DVCR and Chair of HMHREC</td>
</tr>
<tr>
<td>(Deputy Chair)</td>
<td>Appointed by mutual agreement of DVCR, Chair of HMHREC and the TSRAC Chair</td>
</tr>
<tr>
<td>1 Statistician</td>
<td>Appointed by mutual agreement of DVCR, Chair of HMHREC and the TSRAC Chair</td>
</tr>
<tr>
<td>3 members</td>
<td>Nominees to be provide by the Tasmanian Department of Health and Human Services (DHHS), Director of CMO in consultation with the HMHREC and TSRAC Chair’s</td>
</tr>
<tr>
<td>1 member</td>
<td>Menzies Institute for Medical Research Nominees to be provided by the Director of Menzies in consultation with the HMHREC and TSRAC Chair’s</td>
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<tr>
<td>3 discipline specific members</td>
<td>School of Medicine Nominees to be provided by members of the College Leadership Team in consultation with the HMHREC and TSRAC Chair’s</td>
</tr>
<tr>
<td>1 member</td>
<td>School of Health Sciences Nominees to be provided by members of the College Leadership Team in consultation with the HMHREC and TSRAC Chair’s</td>
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<tr>
<td>1 member</td>
<td>Wicking Dementia Research &amp; Education Centre Nominees to be provided by the Director in consultation with the HMHREC and TSRAC Chair’s</td>
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<tr>
<td>1 member</td>
<td>School of Nursing Nominees to be provided by members of the College Leadership Team in consultation with the HMHREC and TSRAC Chair’s</td>
</tr>
<tr>
<td>Additional Members</td>
<td>Discretionary members as deemed appropriate by the Chairs in consultation with the DVCR</td>
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<tr>
<td>Ex officio: Chair, HMHREC</td>
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5 Appointment

The University of Tasmania may recruit members for the TSRAC in such manner and shall appoint them for such periods and on such terms and conditions as it determines, however in ordinary circumstances:
5.1 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 and TSARC Chair’s.

5.2 The Chair will be appointed by the Deputy Vice-Chancellor (Research) and the Chair of the HMHREC following an open call for expressions of interest from HREC (Tas) Network stakeholders including at the University of Tasmanian and at the Department of Health and Human Services.

5.3 The Deputy Chair will be appointed by mutual agreement of DVCR, Chair of HMHREC and the TSARC Chair.

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

5.5 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.

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

5.7 Members may resign their membership by written notice to the TSARC Chair.

5.8 The appointment of any member may be terminated if the TSARC Chair in consultation with the HMHREC Chair, or DVCR of the University of Tasmania determines that it is necessary for the proper and effective functioning of the TSARC.

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

6 Members Responsibilities and Entitlements

6.1 Members will have demonstrable research experience and 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.

6.2 Each Member has the responsibility to:

- Disclose to the TSARC 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 TSARC 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 TSRAC

- 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)

6.3 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 DVCR of the University of Tasmania

6.4 The Chair will receive an annual honorarium at the discretion of the University of Tasmania and support to attend professional development opportunities related to the ethical conduct of research.

7 Chair and Deputy Chair Responsibilities

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

7.1 The Chair must not have other responsibilities that will impair the TSRAC’s capacity as a subcommittee to the HMHREC, 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

7.2 Ensure that TSRAC decisions are informed by an exchange of views from those members who comprise the 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

7.3 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 TSRAC endeavors to reach decisions by general agreement, which need not involve unanimity

7.4 Guide the manner in which the TSRAC communicates with researchers and the decisions about inviting researchers to attend meetings

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

7.6 The Chair or Deputy 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 TSRAC members

8 Accountability

8.1 The TSRAC is accountable to the HMHREC, DVCR of the University of Tasmania and RIEC
for the exercise of its functions and the fulfilment of its roles

8.2 The TSRAC Chair in consultation with the HMHREC 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

9 Meetings

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

9.2 Decisions at meetings will be made following an exchange of views from those members who comprise the membership composition, whether in full attendance or through the receipt and consideration of written comments

9.3 The TSRAC will endeavor to reach decisions by general agreement, which need not involve unanimity

9.4 The TSRAC will record decisions about endorsement, 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), other relevant guidelines and legislation

10 Versioning

These terms of reference shall be reviewed every two years.

<table>
<thead>
<tr>
<th>Former Version(s)</th>
<th>Version 1 – approval Unknown</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 Tasmanian Scientific Research Advisory Committee Chair; endorsed 13 March 2019</td>
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