Tasmanian Scientific Research Advisory Committee

Terms of Reference

1. Objectives

The Tasmanian Scientific Research Advisory Committee (TSRAC) is a committee of the Human Research Ethics Committee (Tasmania) Network. The objective of the TSRAC is to review the scientific validity, merit, integrity and safety of health and medical research applications prior to their consideration by the Tasmanian Health and Medical Human Research Ethics Committee (HREC).

2. Scope

The considerations and recommendations of the TSRAC are subject to the guidelines and requirements of the National Statement on Ethical Conduct in Human Research (NHMRC, 2007), the Australian Code for the Responsible Conduct of Research, relevant institutional policies such as the UTAS Responsible Conduct of Research Policy and all State and Territory regulations and legislation affecting the conduct of research involving human participants, particularly concerning privacy requirements.

3. Specific Functions

The TSRAC will evaluate, according to the National Statement, matters including, but not limited to:

- Clinical data
- Rationale and clinical relevance
- Methodology
- Sample size
- Objectives of the proposed study
- Design issues (placebo controlled, blinding etc)
- Expected outcomes
- Statistical analysis
- Safety and merit
- PICF for accuracy and validity against the protocol
- Relevant expertise of the research team
- Integrity of the proposed study

The TSRAC will provide:
• Assistance and feed-back to researchers and, where appropriate, a reasonable level of advice, to assist researchers to meet the required quality and standards of the National Statement. The committee has the authority to reject proposals outright.

• Endorsement and/or advice to the Health & Medical HREC of the scientific validity and integrity of the research proposal based on the items above. The TSRAC may request the advice of an independent reviewer.

The committee may raise other ethical concerns with the HREC as deemed appropriate by the members.

The TSRAC may be required to work with the HRECs 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. Administrative Support

Administrative and secretarial support, including the communication of decisions made by the committee to both applicants and to the HREC will be provided by the University of Tasmania’s Research Ethics Unit, within the Division of Research.

Agenda papers will be made accessible to members via a secure on-line wiki page as soon as is practicable following the submission deadline, allowing sufficient time for members to access, download and read the papers. A limited number of ‘tabled papers’ may be distributed in the week preceding the meeting.

5. Membership

<table>
<thead>
<tr>
<th>Role/number of members</th>
<th>Responsible Area (School, Unit, Department)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 x Chair of TSRAC &amp; Deputy Chair of Health &amp; Medical Human Research Ethics Committee</td>
<td>Appointed by mutual agreement of DVCR and Chair of H&amp;M HREC</td>
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<tr>
<td>(Deputy Chair)</td>
<td>Elected by TSRAC members</td>
</tr>
<tr>
<td>2 x Statistician</td>
<td>Nominated by Director of Menzies (1) and CEO of Clifford Craig Institute (1)</td>
</tr>
<tr>
<td>1 member (in addition to Statistician)</td>
<td>Nominated by Director, Menzies Research Institute</td>
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<tr>
<td>2 x members (propose: 1 x clinical trial specialist, 1 x oncologist)</td>
<td>Nominated by CMO, Royal Hobart Hospital</td>
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<tr>
<td>1 x senior research delegate</td>
<td>Nominated by Governing Council, THO South</td>
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<tr>
<td>1 x member</td>
<td>Nominated by CMO, Launceston General Hospital</td>
</tr>
<tr>
<td>1 x senior research delegate</td>
<td>Nominated by Governing Council, THO North</td>
</tr>
<tr>
<td>1 x senior research delegate</td>
<td>Nominated by Governing Council, THO North West</td>
</tr>
<tr>
<td>1 member</td>
<td>UTAS School of Pharmacy</td>
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</tbody>
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Version 1 dated March 2013
Nominations for membership of the TSRAC will be issued to respective Heads of Schools/Institution on the completion of membership terms of existing members or as vacancies arise. Appointments will be made by the Deputy Vice-Chancellor (Research) on the advice of the TSRAC Chair and the Chair of the Health & Medical HREC.

Members will have demonstrable research experience and an understanding of the requirements for the ethical and responsible conduct of research involving human participants.

Members will be appointed for two years and may nominate to extend the appointment for subsequent two year time periods conditional on the endorsement of their Head of School/Institution and the Chair of the TSRAC.

Membership will lapse if a member fails to attend three consecutive meetings in person or by delegation to a colleague from the designated School/Institution. Delegations need to be approved in advance of the meeting by the Chair of the TSRAC.

The Deputy Chair will be elected by general agreement of the members of the TSRAC and ratified by the Chair of TSRAC and the Chair of the Health & Medical HREC.

The Chair will be appointed by the Deputy Vice-Chancellor (Research) and the Chair of the H&M HREC 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.

6. Quorum

There is no specified meeting attendance requirements, rather the Chair must be satisfied at the commencement of the meeting that there is sufficient representation from the members for the meeting to proceed. If members are unable to attend, comments on agenda items will be accepted prior to the meeting.

7. Frequency of Meetings

The TSRAC meets monthly. Meeting are held by video-conference between Hobart, Launceston and Burnie. It is a requirement that members read all applications and associated documentation. Members may be required to provide written reviews of applications when requested.
8. **Remuneration**

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.

Members of the TSRAC who are not affiliated with UTAS may elect to seek reimbursement for their time and expenses incurred to a maximum amount per meeting to be determined by HREC (Tas) Network administrators.

9. **Conflict of Interest**

Members should be aware of, and seek to comply with, the University of Tasmania’s ‘Avoiding Conflict of Interest’ policy.

Any member who has an interest or a strong personal view that would unreasonably influence the Committee’s decisions or communication with researchers should declare this at the beginning of the meeting. The Committee will determine if the declaration is a conflict of interest and the member will be asked by the Chair to refrain from entering the discussion when appropriate.