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| Department of Health  **PROCEDURE** | | 2011-03-07 - 2010_TAS_Gov_Logo |
| SOP008\_ETH: Selection and Training of Low Risk Human Research Ethics Committee (LRR Ethics Committee) Procedure | | |
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**Approval**

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**Revision History**

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## Introduction

* This procedure sets out the selection and induction processes for the Tasmanian Department of Health Low Risk Human Research Ethics Committee (LRR Ethics Committee).
* According to the *National Statement on Ethical Conduct in Human Research* (2023 and as amended) (National Statement),Australian institutions, including public health agencies, can establish Human Research Ethics Committees (HRECs) and/or other review bodies to ensure that research carried out within the agency, or under the agency’s auspices, is ethically and scientifically/scholarly sound.
* All institutions establishing ethics review bodies must ensure members have the experience and expertise to undertake high quality reviews of the types of research proposals with which they are likely to be presented, receive appropriate induction, and are supported so that ‘the workload of the review body does not compromise the quality and timeliness of review’ (National Statement 2023, pg. 89).
* Members should be appointed using an open and transparent process.
* Lower risk research is defined in the National Statement as ‘Research in which there is no risk of harm, but in which there is a risk of discomfort and in which there may also be a foreseeable burden (low risk research) OR research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience (minimal risk research)’. Note, both ‘low risk research’ and ‘minimal risk research’ as described in the National Statement, require ethics review.

### Mandatory Requirements

* Members should be appointed for their knowledge, qualities, and experience, and not because they represent a particular organisation or group.
* Appointments will be made for a period of two years with members being able to extend appointments twice, i.e., members may be appointed for a maximum of six years.
* Review of appointments must be undertaken at the end of each two-year period.
* A list of members in each membership category should be maintained for public distribution. Names of members will be made publicly available, with each member’s consent.
* All members must undertake training as part of their induction, and at reappointment. The induction training should include, at a minimum:
  + An introduction to the National Statement (2023 and updates) including, but not limited to, a sound understanding of the principles underpinning the ethical conduct of research, responsibilities and obligations of reviewers, and how to assess levels of risk.
  + An overview of the roles and responsibilities of the Tasmanian Department of Health LRR Ethics Committee, including familiarity with its Terms of Reference.
  + An overview of relevant Tasmanian and National legislation required to effectively undertake reviews and ensure proposed research is compliant with laws related to privacy, data management, etc.
  + Understanding how to undertake an effective and appropriate ethics and scientific/scholarly review.
  + Processes and systems support provided by the Research Ethics Office.
* Training at reappointment will be negotiated with members according to identified needs.
* Additional training should be undertaken in response to changes in legislation or updates to the National Statement (2023) that will impact the reviewing of research, QI, and Audit projects.

### Procedure

#### Establishment Phase

* An advertisement will be circulated through internal and external channels seeking an expression of interest from agency employees and members of the public to become a member of the LRR Ethics Committee.
* Expressions of interest will be submitted electronically via [Tasmanian Department of Health Low Risk Research Ethics Committee – Expression of Interest](https://forms.health.tas.gov.au/232248952391057)
* Records of all applicants will be retained securely in the Research Governance Office’s secure folders and managed by the Research Ethics Office.
* A two-step process will be used to establish the first committee: (1) appointment of LRR Ethics Committee Chairs, (2) appointment of ordinary LRR Ethics Committee members.

#### Selection Phase

**Step 1 – Appointment of Chair**

* A selection panel must be established to review applications for the position of Chair, noting that two Chairs will be appointed to support the work of two LRR Ethics Committees.
* The selection panel should include the Deputy Chief Medical Officer, the Research Governance Coordinator, a nominee from the North/Northwest and a nominee from the South. The regional appointments are required to be endorsed by the Deputy Chief Medical Officer.
* Chairs of the LRR Ethics Committee must be agency employees with considerable research experience and previous membership of an HREC, whose other responsibilities will not impair the LRR Ethics Committees’ capacity to carry out their obligations.
* Chairs must be provided with a formal notice of appointment that specifies:
  + Their responsibilities, including participation, training, confidentiality, and disclosure of interests.
  + Their term of appointment.
  + Any benefits with which they will be provided including administrative and time support.
  + That they are assured legal protection for any liabilities that may arise in the course of the bona fide conduct of their duties as Chairs and as reviewers of research. (See NS 5.1.42)

**Step 2 – Appointment of Ordinary Committee Members**

* An appointment committee must be established to review applications for each of the categories of membership listed in the Terms of Reference.
* The appointment committee should include the Chairs, the Research Governance Coordinator, and any additional nominees determined by the Deputy Chief Medical Officer.
* The appointment committee should appoint against the categories set out in the Terms of Reference, noting that the terms of reference set out a minimum membership and, where possible, select members in addition to that minimum.
* A list of nominees should be provided to the Deputy Chief Medical Officer for review and endorsement.
* Upon endorsement, members will be provided with a formal notice of appointment that specifies:
  + Their responsibilities, including participation, training, confidentiality, and disclosure of interests.
  + Their term of appointment.
  + Any benefits with which they will be provided including administrative and time support.
  + That they are assured legal protection for any liabilities that may arise in the course of the bona fide conduct of their duties as reviewers of research.
  + Additionally, **community members** will be required to complete an *Unpaid Worker Rights, Responsibilities and Confidentiality Agreement,* and provided with information specific to the engagement of unpaid workers/volunteers in the Tasmanian Department of Health.
  + **Community members** will be provided with advice that they will receive support if required to travel for LRR Ethics Committee business.
  + **Community members** will be advised that indemnity is provided through the Tasmanian Government Risk Management Fund as they are deemed unpaid workers/volunteers of a Department of Health committee.

#### Pool of Experts

* Applications for ad hoc membership in a ‘pool of experts’ will be reviewed by the Chairs.
* Upon endorsement, members will be provided with a formal notice of appointment which includes the same information as committee members.
* Additionally, the notice will include the specific details of the categories for which they wish to provide expertise and the yearly time limits they have set.

#### Standing Expression of Interest

* The Research Ethics Office will maintain a standing expression of interest online using the electronic link: [Tasmanian Department of Health Low Risk Research Ethics Committee – Expression of Interest](https://forms.health.tas.gov.au/232248952391057)
* Applicants will be notified within five business days of receipt of their EOI and thanked for their application.
* All EOIs will be forwarded to the Chairs for consideration.
* If the skills of new applicants are judged to significantly add to the LRR Committees, they may be invited to join immediately.
* Alternatively, new applicants will be added, with permission, to the pool of experts.

### Roles and Responsibilities/Delegations

* The **Deputy Chief Medical Officer** provides oversight and guidance in the appointment of LRR Ethics Committee members and ongoing informal oversight. Specific responsibilities include:
  + Appointment of two additional selection panel members for the appointment of Chairs and at their discretion, two additional committee members for the selection of ordinary committee members.
  + Chair the selection committee that appoints LRR Ethics Committee Chairs
  + Review and endorsement of proposed ordinary committee members
  + Informal oversight of LRR Committees through occasional ‘checking in’ with Chairs across the life of their terms of appointment.
* The **Research Governance Coordinator** provides oversight and guidance in the appointment of LRR Ethics Committee members. Specific responsibilities include:
  + Selection of two Chairs in consultation with the selection panel led by the Deputy Chief Medical Officer.
  + Selection of ordinary committee members in consultation with the appointment committee led by the newly appointed Chairs.
* Upon appointment, the **Chairs of the LRR Ethics Committee** will:
  + Meet with the Deputy Chief Medical Officer and Research Governance Coordinator to discuss processes for selection of ordinary committee members, including suggestions related to selection of additional committee members.
  + Co-Chair the selection committee for ordinary committee members.
  + Participate in a panel to select ordinary committee members utilising information in the EOIs.
  + Review and endorse applications for the ‘pool of experts.’
  + Liaise with the Research Ethics Office regarding confirmation letters and other administrative tasks.
* The **Research Ethics Office** will:
  + Receive and forward details of all EOIs to the Deputy Chief Medical Officer, the Research Governance Coordinator, and other nominees as directed.
  + Provide secretariat support to the Deputy Chief Medical Officer, the Research Governance Coordinator, and upon appointment, to the Chairs.
  + Ensure communications to all applicants are in line with direction from the Deputy Chief Medical Officer, Research Governance Coordinator, and the Chairs.

### Key Definitions

* Nil

### Related Documents/Legislation

* [National Statement on Ethical Conduct in Human Research 2023 | NHMRC](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)
* [Low Risk Research Procedure](https://cm.health.local/sdms/showdoc?recnum=P22/332)

### Attachments

1. Low Risk Human Research Ethics Committee Terms of Reference.