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| Department of Health **PROCEDURE** | 2011-03-07 - 2010_TAS_Gov_Logo |
| P015-ETH: Induction of Ethics Committee Members  |
| SDMS Id Number: | P23/345 |
| Overarching Policy: | Research Governance Policy Framework(P20/299) & Low Risk Research Procedure (P22/332) |
| Effective From: | December, 2023 |
| Replaces Doc. No: | NA |
| Custodian and Review Responsibility: | Clinical Quality Regulation and Accreditation (CQRA) |
| Contact: | Research Ethics Officer, Dr Barbara Kameniar  |
| Applies to: | All Staff |
| Review Date: | December 2025 |
| Key Words: | Ethics, LRR Ethics Committee, Pool of Experts, Onboarding, Offboarding |
| Routine Disclosure: | Yes |

**Approval**

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| Prepared by | Dr Barbara Kameniar | Research Ethics Officer | 6165 4004 | 13 October 2023 |
| Through | Dr Raisa Cassim | Research Governance Coordinator | NA | 14 October 2023 |
| Through | RISc | Research Innovation Subcommittee | NA | 15 November |
| Cleared by | Dr Allison Turnock | Deputy Chief Medical Officer | 6166 1322 | 26 November 2023 |

**Revision History**

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| **Version** | **Approved By Name** | **Approved By Title** | **Amendment Notes** |
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### Introduction

* This procedure sets out the standards and requirements with respect to induction of Low Risk Human Research Ethics Committee (LRR Ethics Committee) members and members of the ethics Pool of Experts.
* This procedure also provides direction to support the offboarding of members of the LRR Ethics Committee and/or Pool of Experts.
* The Tasmanian Department of Health, including the Tasmania Health Service, is committed to ensuring its procedures follow the guidance and requirements for ethical conduct of research set out in the *National Statement on Ethical Conduct of Human Research 2023* (the National Statement).
* This procedure satisfies the requirements set out in the National Statement (2023) by ensuring that all new members participate in an induction process prior to commencing their responsibilities.
* This SOP will be revised from time-to-time in response to amendments to the State and National documents that inform it.
* This procedure will be evaluated through the Policy Effectiveness Program.

### Mandatory Requirements

* All members appointed to the LRR Ethics Committee, or the Pool of Experts must participate in an induction process prior to commencing their duties as described in the **LRR Ethics Committee Terms of Reference** and **SOP001 LRR Ethics Committee**.
* All members appointed to the LRR Ethics Committee, or the Pool of Experts are required to take part in education and training related to their roles.
* All members must sign a formal declaration to confirm they understand their roles and responsibilities in terms of declaring conflicts of interest, privacy and reviewing research in line with the National Statement.

### Procedure

#### Induction

* Once a LRR Ethics Committee member, or member of the Pool of Experts has been appointed they will receive a letter that includes the details described in **SOP008 Selection and Training of Ethics Committee**.
* In addition, they will be provided with an ‘Ethics Committee Induction Package’ which will include an electronic copy of the following:
	+ *National Statement on Ethical Conduct of Human Research* (2023)
	+ *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* (2018)
	+ *Australian Code for the Responsible Conduct of Research* (2018)
	+ *LRR Ethics Committee Terms of Reference*
	+ *LRR Ethics Committee National Statement Checklist*
	+ *Guide to logging in to the Ethics Review database and providing electronic feedback to investigators.*
	+ *Unpaid Workers Pre-Engagement Checklist (Community Members Only)*
	+ *Unpaid Workers rights, Responsibilities and Confidentiality Agreement (Community Members Only)*
	+ *Volunteer Agreement Checklist (Community Members Only)*
	+ *Cover for Agency Volunteers* (Community Members Only)
* The Chair of the LRR Ethics Committee, and a representative from the Research Ethics Office or Research Governance Office, will meet with all new members to formally discuss the Ethics Committee Induction Package and outline the rights and responsibilities of members.
* The new member must attend one of the education sessions which are held every six months.
* After the inaugural committee is established, all new members will be invited to observe a meeting, or a number of meetings, prior to taking up duties.
* New members may also be provided with a mentor if one is available, and they would like to work with a more experienced LRR Ethics Committee member.
* All new members will be provided with access to the Ethics review system used by the DoH/THS and provided with training on how to:
	+ *Interpret questions in the Human Research Ethics Application (HREA).*
	+ *Use the electronic system to access applications.*
	+ *Provide* feedback to researchers/investigators about any ethical issues arising from research, QI, or audit projects.

#### Offboarding

* Members who leave the LRR Ethics Committee or the Pool of Experts must receive a letter acknowledging their contribution to ethics review of research, and QI and Audit projects that qualify for ethics review undertaken within the DoH/THS.
* At the time of leaving, members must be offered the opportunity to reflect on their time as a member of the committee or panel of experts with the Chair or the Research Governance Coordinator.
* Access to the Ethics data management system must be removed within **three working days** of a member leaving the LRR Ethics Committee or the Pool of Experts.

### Roles and Responsibilities/Delegations

#### The Research Ethics Office is responsible for:

* Advising the Chair of any new applicants.
* Providing all new members with an ‘Ethics Committee Induction Package’ as outlined above.
* Providing secretariat support for the Chair and new members during the induction process.
* Providing advice about National, State, and organisational requirements as these relate to ethics review processes, as required.
* Ensuring all requisite forms are signed before new members commence their duties.
* Ensuring conviction checks, working with vulnerable people checks, and identity checks have been completed prior to commencing induction. In particular:
	+ Confirming all checks are current for members of staff of the DoH/THS.
	+ Ensuring all checks are current/undertaken for community members.
* Ensuring all new member details are recorded in the system.

#### The Chair is responsible for:

* Providing direction to the Research Ethics Office on when induction can occur.
* Meeting with all new members to formally discuss the Ethics Committee Induction Package and outline the rights and responsibilities of members.
* Advising the Research Ethics Office of any retiring members and providing direction on appropriate offboarding.

#### The LRR Ethics Committee members are responsible for:

* Completing and signing all induction forms in a timely manner.
* Ensuring attendance at regular education sessions.
* Staying up to date with changes to the National Statement.
* Ensuring a sound understanding of use of the ethics review system.
* Seeking assistance from the Research Ethics Office if any questions arise during their induction or at a later time.
* Advising the Chair and/or the Research Ethics Office as soon as practicable if they wish to retire from the LRR Ethics Committee.

#### Members of the Pool of Experts are responsible for:

* Completing, signing, and returning all induction forms in a timely manner.
* Ensuring they attend regular education sessions.
* Staying up to date with changes to the National Statement.
* Ensuring they have a sound understanding of how to use the ethics review system.
* Seeking assistance from the Research Ethics Office if they have any questions related to their induction as it relates to the effective review of ethics application, including the use of the ethics review system, and provision of responses to researchers/investigators.
* Advising the Chair and/or the Research Ethics Office if they wish to retire from the LRR Ethics Committee as soon as practicable.

### Key Performance Indicators

* 100% of members receive the *Ethics Committee Induction Package.*
* 100% of members receive education/training prior to commencing the review of ethics applications.
* 100% of members are offered the opportunity to reflect on their time on the LRR Committee with either the Chair or the Research Governance Coordinator.
* 95% success in removing access to the Ethics data management system is removed within **three working days**.

### Key Definitions

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| Community Members | Community members of the LRR Ethics Committee are volunteers who offer their services, knowledge, skills, and experiences of their own free will to assist in the review of research, quality improvement (QI), and audit projects undertaken within the DoH/THS. They undertake this work to ensure that the conduct of research, QI and audit projects are ethical and to the overall benefit of the people of Tasmania. Community members undertake this work for no financial payment however, they may be reimbursed for expenses incurred as part of their role. Those expenses would generally be agreed upon prior to being incurred and after consultation with the Research Ethics Office and/or the Research Governance Office.  |
| Ethics review | The consideration of research by a HREC or other body such as the LRR Ethics Committee. |
| Human Research Ethics Application Form (HREA) | A national, web-based application form for investigators of all disciplines to complete research ethics proposals for submission to HRECs. The HREA is also used for lower risk applications submitted to the LRR Ethics Committee.  |
| LRR Ethics Committee | The LRR Ethics Committee is constituted within the Tasmanian Department of Health/Tasmanian Health Service to review, evaluate, approve, and monitor lower risk research undertaken within all services for which the Department of Health is responsible e.g., hospitals, ambulances, community health, and related areas such as primary healthcare. Some Quality Improvement (QI) and Audit projects may also require ethics review. |
| Pool of Experts | The Pool of Experts are a group of people with specialist knowledge and/or skills that may be called upon to assist with the review of ethics applications. They may be subject matter experts, research methodology specialist, representative from identified cultural groups, and/or clinicians and/or laypersons with specialist knowledge and expertise. |
| Quality Assurance (QA)/ Quality Improvement (QI)/  | An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a QA/QI activity. Terms such as ‘peer review’, ‘quality assurance’, ‘quality improvement’, ‘quality activities’, ‘quality studies’ and ‘**audit’** are often used interchangeably.  |
| Research | The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative (*Australian Code for the Responsible Conduct for Research, 2018*).  |
| Human Research | “Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through: * taking part in surveys, interviews or focus groups;
* undergoing psychological, physiological or medical testing or treatment;
* being observed by researchers;
* researchers having access to their personal documents or other materials;
* the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
* access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.” (*National Statement on Ethical Conduct in Human Research 2023*).
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### Related Documents/Legislation

* Australian Code for the Responsible Conduct of Research (2018) [Australian Code for the Responsible Conduct of Research, 2018 | NHMRC](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018#block-views-block-file-attachments-content-block-1)
* Cover for Agency Volunteers [TRMF Cover For Volunteers (December 2013) (treasury.tas.gov.au)](https://www.treasury.tas.gov.au/Documents/TRMF-Cover-For-Volunteers-brochure.pdf)
* Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)
* Guide to logging in to the Ethics Review database and providing electronic feedback to investigators.
* LRR Ethics Committee National Statement Checklist
* LRR Ethics Committee Terms of Reference
* National Statement on Ethical Conduct of Human Research (2023)
* SOP001\_ETH Low Risk Human Research Ethics Committee
* SOP008\_ETH Selection and Training of Low Risk Human Research Ethics Committee (LRR Ethics Committee) Procedure
* [Tasmanian Department of Health Low Risk Human Research Ethics Committee – Expression of Interest](https://forms.health.tas.gov.au/232248952391057)
* Unpaid Workers Pre-Engagement Checklist [Unpaid Workers | DHHS and THS Intranet (health.tas.gov.au)](https://doh.health.tas.gov.au/intranet/human_resources/other_workers/unpaid_workers)
* Unpaid Workers rights, Responsibilities and Confidentiality Agreement [Unpaid Workers | DHHS and THS Intranet (health.tas.gov.au)](https://doh.health.tas.gov.au/intranet/human_resources/other_workers/unpaid_workers)
* Volunteer Agreement Checklist [Unpaid Workers | DHHS and THS Intranet (health.tas.gov.au)](https://doh.health.tas.gov.au/intranet/human_resources/other_workers/unpaid_workers)