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| Department of Health **PROCEDURE** | 2011-03-07 - 2010_TAS_Gov_Logo |
| SOP001\_ETH Low Risk Human Research Ethics Committee |
| SDMS Id Number: | P23/311 |
| Overarching Policy: | Research Governance Policy Framework (P20/299) & Low Risk Research Procedure (P22/332) |
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| Contact: | Research Ethics Officer, Dr Barbara Kameniar |
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**Approval**

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| Through | RISc | Research Innovation Subcommittee  |  | September 2023 |
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**Revision History**

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### Introduction

* The purpose of this document is to describe the Low Risk Human Research Ethics Committee (LRR Ethics Committee) system implemented by the Tasmanian Department of Health (DoH) to protect the interests of human participants in low risk research, Quality Improvement (QI), and Audit activities across the system and to facilitate the conduct of that research, QI, and Audit projects.
* This procedure outlines the role and function of the LRR Ethics Committee and the Research Ethics Officer (REO).

### Mandatory Requirements

* The LRR Ethics Committee is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (2023, and as amended) (The National Statement) and relevant state and national legislation, regulations, and guidelines. All proceedings of LRR Ethics Committees are strictly confidential.
* It is the responsibility of the LRR Ethics Committee to ensure that all low risk human research, quality improvement (QI) or audit projects within the publicly funded Tasmanian Health Sector is conducted according to The National Statement.
* It is the responsibility of the LRR Ethics Committee to submit reports annually relating to its activity. These include, but are not limited to:
* National Health and Medical Research Council (NHMRC)
* Australian Health Ethics Committee (AHEC)
* Health Complaints Commissioner Tasmania
* Tasmanian Health Services Executive Committee

The LRR Ethics Committee will provide information to any assessor or accreditation body upon request in order to comply with national standards such as the National Safety and Quality Health Service standards (NSQHS) of the ACSQHC.

### Roles and Functions of the LRR Ethics Committee

* 1. **Ethical Review of Low Risk Research, QI, and Audit Projects at the Tasmanian Department of Health**

The LRR Ethics Committee specialises in reviewing research, QI, and audit projects that are of lower risk to research participants and/or to others e.g., family members, specific social groups. Any research, QI, or audit proposal that constitutes more than a low risk needs to be reviewed by a Human Research Ethics Committee (HREC). The Research Governance and Research Ethics Offices provide advice on the most appropriate HREC for submission of applications that have a higher risk.

* 1. **LRR Ethics Committee**
		1. **Constitution**

The LRR Ethics Committee is comprised of a range of representatives from varied backgrounds and, as closely as possible, reflects the membership categories of an HREC as stipulated by The National Statement (2023). Specific details can be found within the **LRR Ethics Committee Terms of Reference**.

The LRR Ethics Committee also maintains a “pool of experts”. These experts include subject matter experts, research methodology specialists, representatives from identified cultural groups, and clinicians with specialist knowledge and expertise to provide advice on specific matters related to any research project. The LRR Ethics Committee may seek the assistance of additional experts as it chooses or deems necessary.

The Committee’s methodology is to reach decision through discussion and consensus agreement.

* + 1. **Role**

The primary role of the LRR Ethics Committee is to consider ethical aspects of human research in accordance with the requirements of The National Statement and relevant state and national legislation, regulations and guidelines. One part of this is the review and, as appropriate, approval or rejection of new research projects and amendments submitted by researchers. The LRR Ethics Committee also plays an important role in the ongoing monitoring of research projects it has approved.

For further information about the approach to review of low risk research projects, refer to the National Statement Checklist on the Research Ethics website.

* + 1. **Meeting Schedule**

There will be two LRR Ethics Committees constituted. Each LRR Ethics Committee will meet once a month, except during December and January when only one Committee will meet. This schedule ensures two LRR Ethics Committee meetings each month. Scheduled meetings and submission due dates are posted on the Research Ethics website.

* 1. **Subcommittee – Expedited Review Subcommittee**
		1. **Constitution**

An expedited review subcommittee (the subcommittee) comprising the Chair and two other members of the LRR Ethics Committee, which must include at least one community member, may be appointed from time to time. Subcommittee membership may change if any conflict of interest issues (real or perceived) arise, when a member is not available, or when the LRR Ethics Committee believes a member has specific knowledge and skills applicable to an application under review. Appointment to the subcommittee will be made by the LRR Ethics Committee.

The subcommittee’s methodology is to reach decisions through discussion and consensus agreement.

* + 1. **Role**

The subcommittee review process allows for review of selected matters outside of formal meeting times.

For selected matters, the subcommittee is permitted to provide approval via delegation. The following are examples of such matters:

* Amendments to approved research projects
* Responses from researchers to feedback from the committees

Decisions undertaken by the subcommittee must be reviewed by the LRR Ethics Committee at its next meeting.

* + 1. **Meeting Schedule**

Each subcommittee meets once a month, except December and January, between full meetings of the LRR Ethics Committee. Scheduled meetings and submission due dates are posted on the Research Ethics website.

* 1. **External Experts**

If an expert opinion is required, which cannot be found within the existing LRR Ethics Committee structure, including among the established “pool of experts”, the opinion of an external expert will be sought. Any expert external to the Department of Health and the Tasmanian Health Service much sign an Agreement for the Conduct of Expert Review. The Agreement incorporates conditions of the review as well as a confidentiality agreement and a declaration of private interest form. The contract must be signed prior to the expert receiving any project material for review.

* 1. **The Research Ethics Officer**

The LRR Ethics Committee and subcommittee are supported by a Research Ethics Officer (REO). The LRR Ethics Committee and subcommittee delegate all communication and correspondence to the REO.

For more information about the role of a REO, refer to SOP002\_ETH: Ethical Review Administration.

* + 1. **LRR Ethics Committee Communication**
			1. **Communication with the LRR Ethics Committee(s) or subcommittee(s)**

Communication between sponsors and/or researchers and their delegates and the LRR Ethics Committee(s) or subcommittees may happen as follows:

* In writing. Sponsors and/or researchers and their delegates may write a letter, email, or memo; or
* In person. A researcher may be invited to attend a LRR Ethics Committee or subcommittee

All contact between sponsors, researchers, and their delegates and the LRR Ethics Committee(s) and subcommittees is via the REO. This is to ensure all communications are appropriately tracked and any determinations stored.

* + - 1. **Researchers’ Request to attend the LRR Ethics Committee(s) or Subcommittee**

If a researcher requests to attend a LRR Ethics Committee or subcommittee, the following must occur:

* The researcher must contact the Research Ethics Office and make them aware of the request.
* A REO will confirm with the researcher the appropriate meeting they should attend, and then ensure that the relevant project has been/will be put on the meeting agenda.
* Once Confirmed, the researcher will be informed that they are welcome to attend the meeting and a date and time of attendance will be agreed.
* A record of the researcher’s attendance will be captured in the meeting minutes and the outcome of the visit will be recorded.
	+ 1. **LRR Ethics Committee or Subcommittee Request for Researcher Attendance**

If the LRR Ethics Committee(s) or subcommittee(s) request to have a researcher attend a meeting, the following must occur:

* The LRR Ethics Committee(s) or subcommittee(s) must inform the Research Ethics Office of the request.
* A REO should then contact the researcher and inform them of the Committee’s or subcommittee’s request.
* The researcher will either accept or decline the Committee’s or subcommittee’s invitation.
* If accepted, a date and time of attendance will be agreed.
* A record of the researcher’s attendance will be captured in the meeting minutes and the outcome of the visit will be recorded.
* If not accepted, a record of the decline and reasons for the decline, if provided, will be recorded.
	+ 1. **Observer Attendance at Meeting**

If an observer is invited or requests to attend a LRR Ethics Committee or subcommittee meeting, the following must occur:

* Invitation
	+ The REO should contact the observer and inform them of the invitation to attend.
	+ The REO will inform the Chair of the invitee’s response.
* Request
	+ The REO should contact the chair and inform them of the request to attend.
	+ The Chair may request a copy of the requestee’s CV.
	+ The REO should inform the observer of acceptance of the attendance request.
* The REO will inform the observer as to the confidential nature of the discussions and if they are external to the Tasmanian Department of Health, they will be requested to sign a Confidentiality Agreement. DoH staff are bound to confidentiality by their employment under the State Service Act.
* A record of the observer’s attendance will be captured in the meeting minutes.
	1. **Fees**

The DoH charges fees for ethics review of new research projects, amendments, and other items submitted to the LRR Ethics Committee(s). The fees to be charged are set by the DoH and may change from time to time. The current fee schedule is available on the Research Governance Office webpage.

### Key Performance Indicators

New projects, amendments and other items for review are reviewed in accordance with this SOP. All ethics reviews should be complete within 60 days of first submission, subject to researcher response times.

### Key Definitions

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| Tasmanian Department of Health (DoH) | The Tasmanian Department of Health is responsible for hospitals, ambulances, community health, and related areas such as primary healthcare. |
| Ethical review | The consideration of research by a HREC or other body such as the LRR Ethics Committee. |
| Ethical approval | A determination by an ethical review body that a research project satisfies ethical standards and requirements, of the NHMRC, National Statement on Ethical Conduct in Human Research 2023 (National Statement). |
| Evaluation | The systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity. The term is used in a broad sense to refer to any set of procedures, activities, resources, policies and/or strategies designed to achieve some common goal or objective. |
| Higher risk Research | Research in which there is a risk of harm and in which there may also be a foreseeable burden. The risk of harm in higher risk research may or may not be a risk of significant harm and may be a harm on the individual, group, community, societal or global level (see NS Chapter 2.1, Figure 1) |
| 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.  |
| Human Research Ethics Committee (HREC) | An institution that has established an ethical review body in accordance with NHMRC, National Statement on Ethical Conduct in Human Research 2007 (National Statement) to conduct the scientific and ethical review of research. Internationally, HRECs may be referred to as an Institutional Review Board (IRB) and Institutional Ethics Committee (IEC). |
| Lower risk research | 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 or harm or discomfort, but which includes a potential for minor burden or inconvenience (minimal risk research). |
| National Certification Scheme of Institutional Processes Related to the Ethical Review of Multi-centre Research | The certification of HRECs pertains to the certification of their sponsoring institution. To be identified as a ‘Certified Institution’, the institution’s ethical review process has undergone an independent assessment conducted by the NHMRC. Certification is dependent upon a satisfactory demonstration of institutional conformance with specified criteria which, in part, are based on the National Statement - including that the HREC is appropriately constituted, and that its institution’s policies, processes and procedures meet an agreed national set of criteria. A list of institutions with certified ethics review processesis available from the NHMRC.**NB: Under review in 2023** |
| National Mutual Acceptance (NMA) | The system of single scientific and ethical review of multi-centre human research projects across Australian jurisdictions (public health organisations only) whereby one certified HREC provides the ethical review for a research proposal that is accepted by the other institutions participating in the multi-centre research. [National Mutual Acceptance - Clinical Trials and Research](https://www.clinicaltrialsandresearch.vic.gov.au/national-mutual-acceptance) |
| Non-HREC level alternative | A person or body (e.g., specifically constituted committee, subcommittee or delegate) that conducts an ethical review of a research project as an alternative to that of a full HREC. The LRR Ethics Committee is one such non-HREC level alternative. |
| Multi-Centre Research | Research that is conducted at more than one site within the Australian public health system.  |
| Participant Information and Consent Form (PICF) | The PICF is a fundamental project document in research involving humans. It is designed to communicate information about a research project to potential participants. It outlines the aims and objectives of the study, why the study is important (benefits), what will be required of participants, any potential risks/burdens associated with the research, the rights of participants, and how information about them will be managed. The PICF also provides potential participants with a mechanism by which they can give their consent, if they choose to do so. |
| 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*).  |
| Single-Centre Trial | Research that is conducted at one site only (i.e., single-site research).  |
| Single Ethics Review | A process whereby one certified HREC provides the ethics review for a research proposal that is accepted by other institutions participating in the multi-centre research. See also National Mutual Acceptance. |
| Site (institution) | Any public or private entity or medical facility where research is conducted. |
| Site-Specific Assessment (SSA) | A mechanism used by the health service to ensure that the proposed research project complies with governance requirements, and to consider whether the research should be conducted and supported at the proposed site. |
| Site Assessment | A process that assesses research against institutional capacity, requirements, and strategies and any applicable jurisdictional requirements (including legal obligations). The outcome of a site assessment is site authorisation: a determination by an organisation that a research project to be conducted at one or more of its sites or under its auspices satisfies organisational requirements and may commence at the site/s over which it exercises its authority. |
| Site Principal Investigator | The site principal investigator is the person responsible, individually or as a leader of the clinical trial or research team at a site, for the conduct of a clinical trial or research at that site. The site principal investigator ensures clinical trials or research undertaken at a specific research site is in accordance with the approved protocols.[Fact sheet 8: National Clinical Trials Governance Framework – Roles and functions for site principal investigator (safetyandquality.gov.au)](https://www.safetyandquality.gov.au/sites/default/files/2020-02/fact_sheet_8_national_clinical_trials_governance_framework_-_roles_and_functions_-_site_principal_investigator.pdf) |

### Related Documents/Legislation

In addition to the documents listed below, researchers should consult the Research Ethics Office website for advice and any forms required for submissions. The DoH uses REGIS for all low risk research, QI and audit projects. For advice on the most appropriate HREC to which to submit any more than low risk projects, contact the Research Ethics Office at research.ethics@health.tas.gov.au or on (03) 6165 4004, or the Research Governance Office.

### INTERNAL DOCUMENTS

Research Governance Policy Framework(P20/299)

Low Risk Research Procedure (P22/332)

SOP002\_ETH Ethical Review Administration

SOP003\_ETH Handling Conflict of Interest in Ethical Review of Research

ToR Low Risk Ethics Committee Terms of Reference

### EXTERNAL DOCUMENTS

National Statement on the Ethical Conduct in Human Research (2023, and as amended)

NHMRC Guidelines approved under s95a of the *Privacy Act 1988* (2015)

Personal Information Protection Act 2004

Australian Code for the Responsible Conduct of Research, 2018

### FURTHER INFORMATION

For enquiries related to this Procedure please email research.ethics@health.tas.gov.au