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| Department of Health**PROCEDURE**  | 2011-03-07 - 2010_TAS_Gov_Logo |
| P003-ETH: Managing Conflicts of Interest |
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| 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 |
| Applies to: |  |
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**Approval**

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| Prepared by |  |  |  |  |
| Through | Dr Raisa Cassim | Research Governance Coordinator | NA | 29 September 2023 |
| Through | RISc | Research Innovation Subcommittee | NA | 15 November 2023 |
| Cleared by | Dr Allison Turnock | Deputy Chief Medical Officer | 6166 1322 | 24 November 2023 |

**Revision History**

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### Introduction

* This procedure sets out the Low Risk Human Research Ethics Committee (LRR Ethics Committee) standards and requirements with respect to conflicts of interest that may arise from proposals to conduct research, and Quality Improvement and Audit projects that qualify for ethics review within the Agency (from this point called the Tasmanian Department of Health (DoH)). It is intended to complement *The State Service Code of Conduct* ([The State Service Code of Conduct (health.tas.gov.au)](https://doh.health.tas.gov.au/intranet/human_resources/documents/conduct/code_of_conduct) that applies to a broad spectrum of activities of DoH employees.
* This procedure defines a conflict of interest as a situation “where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests. In the context of research, it exists where a person’s individual interests or responsibilities have the potential to influence the carrying out of their institutional role or professional obligations in research or where an institution’s interest or responsibilities have the potential to influence the carrying out of its research obligations” (NS, p. 105).
* Interests can be financial, personal, familial, professional, or organisational. Real or perceived conflicts of interest raise concerns about individual or institutional integrity and have the potential to erode public trust in research, and they must be managed.
* In identifying and managing potential, perceived or actual conflicts of interest, the following principles taken from the National Health and Medical Research Council (NHMRC) Policy on the Disclosure of Interests, should be used as a guide:
	+ Disclosure – interests will be fully declared and actively reviewed.
	+ Decision – decision making processes will be transparent and unbiased.
	+ Diligence – conflicts of interest will be managed in a manner that is diligent, timely and transparent.
* This document describes processes regarding the LRR Ethics Committee member conflicts of interest in order to comply with the National Statement (2023) and in order to respect the expectations of the community and other stakeholders in the process by which research is reviewed by Human Research Ethics Committees more broadly.
* This procedure satisfies the requirements set out in the National Statement (2023).
* This procedure applies to researchers and all other staff members involved in research activities at the DoH. It applies to all LRR Ethics Committee members, subcommittee members and invited experts involved in the review of research proposals at the DoH.
* This procedure also applies to conflict of interest for single site and multisite research for which the LRR Ethics Committee was the reviewing body.
* This procedure 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 researchers and all other staff involved in research at the DoH, all committee and subcommittee members, all members of the pool of experts, all invited experts involved in research review, and all members of the Research Ethics Office must follow and comply with the information set out in this procedure.
* Researchers must be aware of potential conflict of interest in the conduct of research and appropriately disclose perceived, potential, and actual conflicts of interest during the project review process.
* Committee and subcommittee members must disclose actual, potential, and perceived conflicts of interest and **abstain from participating in decision-making** in relation to those projects in which the conflict (actual, potential, or perceived) arises. Similarly, invited experts are also required to disclose perceived, potential, and actual conflicts.

### Roles and Responsibilities

#### The Researchers/Investigators are responsible for:

* **Disclosing any conflicts of interest, whether actual, potential, or perceived.**
* Ensuring that any conflict of interest, whether actual, potential, or perceived in no way influences:
	+ The selection of participants in a research project.
	+ The protection of the privacy and other rights of research participants.
	+ The interpretation and use of the data, outcomes, and results of a research project.

#### The LRR Ethics Committee is responsible for:

* Disclosing any conflicts of interest, whether actual, potential, or perceived to the Research Ethics Office and to the LRR Ethics Committee of which they are a member.
* Ensuring that any conflict of interest, whether actual, potential, or perceived of themselves or researchers/investigators in no way influences:
	+ The rigour of the processes used to review and approve proposed research projects.
	+ The selection of participants in a research project.
	+ The protection of the privacy and other rights of research participants.
	+ The interpretation and use of the data, outcomes, and results of a research project.

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

* Keeping records of any conflicts of interest, whether actual, potential, or perceived.
* Advising the Chair and the LRR Ethics Committee of any conflicts of interest prior to each LRR Ethics Committee meeting, through the agenda circulated prior to the meeting.

#### Members of the Pool of Experts and Ad hoc Reviewers are responsible for:

* Disclosing any conflicts of interest, whether actual, potential, or perceived to the Research Ethics Office and/or to the Chair of the LRR Ethics Committee.
* Ensuring that any conflict of interest, whether actual, potential, or perceived of themselves or researchers/investigators in no way influences:
	+ The rigour of the processes used to review and approve proposed research projects.
	+ The selection of participants in a research project.
	+ The protection of the privacy and other rights of research participants.
	+ The interpretation and use of the data, outcomes, and results of a research project.

### Procedures of the LRR Ethics Committee

### Conflicts of Interest Involving Researchers

#### All researchers must disclose the following to the LRR Ethics Committee and its subcommittee via the Human Research Ethics Application (HREA):

* All aspects of the funding and other support of the project that would be pertinent to the committee’s deliberations regarding the project.
* Provision of details about former or recent relationships with research sponsors.
* Any financial or other interests in any entity contributing to the funding or other support of the project.
* Any significant change in either the funding or other support of the research project or in the nature or extent of the interests of the researcher over the course of the project. This requirement applies to any stage of the project up to and including the last publication of data, outcomes or results derived from the project.
* Any involvement in competing research (see NS 2023: 5.3.11, 5.3.12)
* Any other matter that could lead to an actual, potential, or perceived conflict of interest.

#### Conflict of Interest shall be managed as follows:

* All aspects of funding/support must be disclosed.
* The LRR Ethics Committee shall determine the extent of disclosure of interests required, for example, the LRR Ethics Committee may require the information be disclosed to research participants and/or disclosed in presentations or publications or other research outcomes, or determine the research not be conducted. (For additional possible measures, see National Statement, 2023, 5.6.7)
* The LRR Ethics Committee shall then inform the researcher of the extent of disclosure of interest required to be included in any participant information and consent forms.

#### Conflicts of Interest Involving Committee and Subcommittee Members

* **Any member of the LRR Ethics Committee or Pool of Experts must disclose the following:**
	+ Any actual, potential, or perceived conflict of interest, in any research project that is submitted for consideration by the committee. These interests may include any personal involvement or participation in the research, any familial, personal, or financial interest in the outcome of the research, or any involvement in competing research.
* **Disclosure of Conflicts of Interest shall be handled as follows:**
	+ The National Statement (2023) indicates that measures related to a conflict of interest of committee members should be tailored to individual circumstances.
	+ In the first instance, a member who has identified they have a conflict of interest should consider absenting themselves from any deliberations of the LRR Ethics Committee.
	+ If the committee member determines they can stay, they must discuss this determination with the Chair who shall determine whether the member’s interests constitute a conflict of interest.
	+ If those interests are deemed to create a conflict of interest or could reasonably been perceived as a conflict of interest, then the member must abstain from participating in the process by which the LRR Ethics Committee or subcommittee makes a determination in relation to that research.
	+ When this occurs, agendas may be reorganised so that the research under review is discussed last, so the members with the actual, potential or perceived interest is present for deliberations of all other projects.
	+ Disclosures of interest, determinations related to whether the interest is a conflict of interest, and how this was managed shall be recorded in the minutes of the meeting.
	+ An abstention letter may be sent to communicate the handling of the conflict of interest.
	+ LRR Ethics Committee members should sign a “Declaration of Interest Form” to declare any potential conflicts with the deliberations of the Committee annually or when their circumstances change.
	+ All completed forms must be kept in the Research Ethics Office.

#### Conflicts of Interest Involving Independent/Expert Reviewers or member of the Pool of Experts

* **Expert reviewers or members of the Pool of Experts who provide the LRR Ethics Committee and/or subcommittee with independent expert comments must:**
	+ Sign a “Review Contract” which contains a “Declaration of Interest Form” to declare any potential conflicts prior to participating in the review.
	+ Sign a Confidentiality Agreement form if they are not employees of the DoH/THS.
	+ All completed forms should be scanned and added to the electronic file for the meeting, held in the Research Ethics Office.

#### Key Performance Indicators

* 100% of LRR Ethics Committee members, including members of the Pool of Experts will have completed, signed, and returned the Conflict-of-Interest Declaration prior to reviewing any applications.
* 90% of all conflicts of interest related to projects under review will have been identified and managed prior to any LRR Ethics Committee meeting.
* 100% of all projects will be reviewed by LRR Ethics Committee members, including members of the Pool of Experts, who do not have a conflict of interest in reviewing the specific project under review.

### Key Definitions

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| Conflict of Interest | The National Statement (2023) provides a detailed discussion of what a conflict of interest might be and why it is important to identify and manage such conflicts. No explicit definition is provided within the National Statement. The fuller discussion is included here to aid determinations.*A conflict of interest exists where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests. In the context of research, it exists where a person’s individual interests or responsibilities have the potential to influence the carrying out of their institutional role or professional obligations in research or where an institution’s interests or responsibilities have the potential to influence the carrying out of its research obligations.**While a conflict may relate to financial interests, it can also relate to personal, familial, professional or organisational benefits or advantages that depend significantly on or could unduly influence research outcomes.**The perception that a conflict of interest is not properly identified or managed is a serious matter and can raise concerns about the integrity of individuals or the management practices of the institution, potentially undermining community trust in research.**Whether an activity or an affiliation, association or relationship gives rise to a conflict of interest is a determination to be made by the appropriate decision maker. In making this determination, it should be recognised that having multiple interests does not necessarily constitute a conflict of interest and that having a conflict of interest does not, in itself, imply improper motivation or individual wrongdoing.* |
| 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.  |
| 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

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 lower risk research, Quality Improvement, and Audit projects. For advice on the most appropriate HREC to which to submit any higher risk research projects, contact the Research Ethics Office at research.ethics@health.tas.gov.au or the Research Governance Office at research.governance@health.tas.gov.au.

#### Internal Documents

* Research Governance Policy Framework(P20/299)
* Low Risk Research Procedure (P22/332)
* SOP001\_ETH Low Risk Human Research Ethics Committee
* SOP002\_ETH Ethics Review Administration
* Low Risk Ethics Committee Terms of Reference
* State Service Code of Conduct ([The State Service Code of Conduct (health.tas.gov.au)](https://doh.health.tas.gov.au/intranet/human_resources/documents/conduct/code_of_conduct)

#### External Documents

* Australian Code for the Responsible Conduct of Research, 2018
* National Statement on the Ethical Conduct in Human Research (2023)
* NHMRC Guidelines approved under s95a of the Privacy Act 1988 (2015)
* Personal Information Protection Act 2004
* [policy-on-the-disclosure-of-interests-requirements.pdf (nhmrc.gov.au)](https://www.nhmrc.gov.au/sites/default/files/documents/attachments/publications/policy-on-the-disclosure-of-interests-requirements.pdf)

### Further Information

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