

La Trobe Human Research Ethics Committee

Terms of Reference

INTRODUCTION

The La Trobe University Human Research Ethics Committee (La Trobe HREC) is the institutional human research ethics committee for La Trobe University (LTU). It has been established to ensure that human research is designed and conducted ethically whilst protecting the welfare and rights of participants and researchers, in accordance with the [National Statement on Ethical Conduct in Human Research](#)¹ (the National Statement) and the [Australian Code for the Responsible Conduct of Research](#)² (the Code).

The La Trobe HREC is registered with the National Health and Medical Research Council (EC00226).

Scope of Responsibilities

National Statement 5.1.29(a)

The La Trobe HREC provides expert review of research proposals submitted for ethical approval by LTU staff and students. In doing this, the committee aims to:

- provide independent, competent and timely review of human research proposals in respect of their ethical acceptability;
- protect the mental and physical welfare, rights, dignity and safety of research participants.
- facilitate ethical research through efficient and effective review processes;
- promote an awareness and understanding of human research ethics within LTU and the broader community;
- review human research in accordance with the National Statement, the Code and other national guidelines and legislative instruments, and;
- provide oversight, monitoring and advice on ethical aspects of human research.

The HREC shall:

- consider ethical dimensions of proposed research projects involving humans and determine whether they are acceptable on ethical grounds, consistent with the values of research merit and integrity, respect for human beings, justice and beneficence and meet relevant requirements of the National Statement and any other requirements;
- acknowledge and consider any prior peer review which has judged that a project has research merit when conducting reviews;
- ensure that any unnecessary duplication of ethical review is minimised;
- maintain a record of all human research projects that are considered;
- participate in the monitoring human research projects throughout their lifecycle;
- consider and approve, as appropriate, proposed modifications to approved projects;
- consider and approve, as appropriate, annual and final reports of approved projects;
- participate in the consideration and investigation of adverse events and other safety reports for projects approved by the La Trobe HREC;

¹ National Health and Medical Research Council, Australian Research Council and Universities Australia (2025). *National Statement on Ethical Conduct in Human Research*. Canberra: National Health and Medical Research Council.

² National Health and Medical Research Council (2018). *Australian Code for Responsible Conduct of Research*.

- participate in the review and investigation of complaints regarding human research approved by the La Trobe HREC or the institutional low-risk procedures in alignment with the [La Trobe Research Misconduct Procedure](#) and in consultation with the 'Designated Person' under the Code;
- maintain communication with internal and external stakeholders and promote ethically good human research at LTU;
- assist LTU in the preparation of reports, relating to HREC operations and human research ethics, as needed;
- provide input to LTU policies and procedures, which relate to human research ethics, as needed, and;
- manage appropriately any conflicts of interest (actual, perceived or potential) involving the La Trobe HREC, its members or advisors.

In discharging its responsibilities, the La Trobe HREC may consult with relevant subject matter experts and/or regulatory and advisory bodies, as it chooses.

RELATIONSHIP TO OTHER PROCESSES OF RESEARCH REVIEW

National Statement 5.1.29(b)

Low-Risk Research

In accordance with the National Statement 5.1.10 – 5.1.14, LTU has established a non-HREC pathway for low-risk human research ethical review. The Low-Risk Ethics Assessment Panel (LEAP) has been designated for the review of low-risk research across LTU. Terms of Reference for the LEAP are documented separately.

Where the LEAP determines that a research proposal requires HREC review, due to risk level or other concerns under the National Statement, the research proposal is to be referred to the La Trobe HREC.

The LEAP reports on its activities as a standing item at the La Trobe HREC regular meetings. LEAP activities are included in reporting to the LTU Research and Graduate School Committee (RGSC).

Multi-centre research

In line with the National Statement, LTU seeks to minimise the duplication of ethical review by accepting reviews done by NHMRC-registered HRECs in Australia. Consideration may be given to ethical reviews by other institutions with policies and procedures based on the Declaration of Helsinki.

To facilitate multi-centre research the La Trobe HREC may:

- communicate with any other HREC.
- provide its scientific/technical and/or ethical assessment of the research to another HREC.

Exemption of Research from Ethical review

In accordance with the National Statement 5.1.10 – 5.1.14, LTU has established a pathway for researchers to request assessment and a grant of exemption from ethical review. Exemptions are an institutional governance responsibility, however, a list of projects granted exemption will be provided to the HREC quarterly at which time, the La Trobe HREC may request details on the exemption.

RELATIONSHIP TO NON-AFFILIATED RESEARCHERS***National Statement 5.1.29(c)***

The La Trobe HREC may provide ethical review and monitoring for research proposals, on a case-by-case basis, for researchers external to LTU where the research involves:

- LTU staff or students, their information (data) and/or tissue as participants;
- Participant recruitment through a service provided by LTU;
- LTU as a research site;
- funding, endorsement or sponsorship by LTU, and;
- members of an external entity that has a formal agreement with LTU that specifically includes ethical review.

The La Trobe HREC may provide ethical review as part of an agreement between LTU and an external organisation.

Non-affiliated researchers receiving ethical review and approval through the La Trobe HREC will be subject to all compliance as outlined in the application process.

MECHANISMS FOR ACCOUNTABILITY AND REPORTING***National Statement 5.1.29(d)*****Accountability**

The La Trobe HREC is the institutional human research ethics committee for LTU on all its campuses, national and international.

Within La Trobe, the committee is accountable to the Deputy Vice-Chancellor (Research and Industry Engagement) (DVCRIE) through the Research and Graduate Studies Committee (RGSC) in the conduct of its regular business.

Reporting

The La Trobe HREC will provide:

- an annual report to the National Health and Medical Research Council in accordance with the National Statement paragraph 5.7.4;
- an annual report (based on a calendar year) to the DVCRIE through the RGSC, and;
- regular updates on areas of risk, HREC activities and performance indicators to the RGSC.

Reporting to RGSC will be shared with Academic Board and the Council Governance, Audit and Risk Committee.

MEMBERSHIP***National Statement 5.1.29(e)***

The membership of the HREC is prescribed by the National Statement, paragraph 5.1.30 (a-f). As such the La Trobe HREC minimum membership shall include at least:

- a chairperson with suitable experience, including significant experience on an HREC and whose other responsibilities will not impair their ability to carry out their obligations (Category A);
- at least two people, who have no affiliation with LTU, who bring a broader community or consumer perspective and have no paid affiliation with La Trobe (Category B);

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- at least one person with knowledge of, and current experience in, the professional care or treatment of people (Category C);
- at least one person who performs a pastoral care role in a community (e.g., an Aboriginal elder or minister of religion) (Category D);
- a qualified lawyer, where possible one who is not engaged to advise LTU (Category E); and
- at least two people with current research experience that is relevant to research proposals to be considered at meetings they attend (Category F).

The membership will seek to include Aboriginal or Torres Strait Islander members, who may be academic staff members at the University. Such members may be in addition to the minimum membership or may represent one of the minimum membership categories (National Statement 5.1.33).

The membership may include up to two higher degree research students both to represent a part of the LTU community and as a training mechanism. These members would be listed as research members but will not be included as part of the minimum membership requirements.

Normally, a Category F member of the La Trobe HREC will be appointed Deputy Chairperson to assist with the operation of the La Trobe HREC.

HREC may invite any person to attend a meeting, to either provide expertise/advice, or act as an observer.

REMUNERATION***National Statement 5.1.29(f)***

La Trobe HREC members who are non-La Trobe staff or students shall receive an honorarium for each meeting attended.

La Trobe will provide all HREC and LEAP members with legal protection in respect of liabilities that may arise during bona fide conduct of their duties.

ETHICAL REVIEW FEES***National Statement 5.1.29(g)***

Fees will not be charged for applications to the La Trobe HREC for research conducted by La Trobe researchers or administered by La Trobe.

Ethical review fees for external entities will be managed in accordance with their relevant agreements.

In the absence of an agreement, fees may be charged for applications submitted to the La Trobe HREC from external researchers or entities with no formal affiliation with LTU. These researchers will be invoiced according to the LTU fee structure which is made available on the La Trobe HREC website.

La Trobe HREC members who are non-La Trobe staff or students shall receive an honorarium for each meeting attended.

REVISION OF TERMS OF REFERENCE

These Terms of Reference will be reviewed as necessary in response to changes in legislation, policies or upon the request of the La Trobe HREC, or every three years, whichever occurs first.

RELATED DOCUMENTS**Guidelines & Legislation**

- [Australian Code for the Responsible Conduct of Research 2018](#)
- [National Statement on Ethical Conduct in Human Research 2025](#)
- [Privacy and Data Protection Act 2014 \(Victoria\)](#)
- [Privacy Act 1988](#)
- [The Public Records Act 1973 \(Vic\)](#)
- [Health Records Act 2001 \(Vic\)](#)

La Trobe University Policies and Procedures

- [Conflict of Interest Policy](#)
- [Research Clinical Trials Policy](#)
- [Research Data Management Policy](#)
- [Research Governance Policy](#)
- [Research Human Ethics Procedure](#)
- [Research Integrity Policy](#)
- [Research Misconduct Procedure](#)

APPROVAL

The La Trobe HREC's Terms of Reference were last approved by the RGSC on 6 March 2024.