

# Research Human Ethics Procedure

## Section 1 - Key Information

<b>Policy Type and Approval Body</b>	Academic - Academic Board
<b>Accountable Executive - Policy</b>	Deputy Vice-Chancellor (Research and Innovation)
<b>Responsible Manager - Policy</b>	Executive Director, Research Office
<b>Review Date</b>	19 November 2028

## Section 2 - Purpose

(1) Research conducted with or about people or their data or tissue raises ethical considerations that govern the standards of conduct. It may also expose research participants to significant risks. Human research is governed in Australia by the [National Statement on Ethical Conduct in Human Research \(2023\)](#) (National Statement). The purpose of the [National Statement](#) to promote ethically sound research that accords participants with the respect and protection that is due to them and is of benefit to the wider community.

(2) La Trobe University has established policies and procedures to ensure that human research conducted by La Trobe staff and students conforms to the [National Statement](#), other relevant legislative requirements and current best practice. The University's human research ethics review bodies are responsible for ensuring compliance with the [National Statement](#) reviewing, approving and monitoring all human research conducted by La Trobe staff and students.

## Section 3 - Scope

(3) Refer to the [Research Governance Policy](#).

## Section 4 - Key Decisions

Key Decisions	Role
Reviewing, approving and monitoring research submissions involving human participants	HREC and LEAP (or delegate)

## Section 5 - Policy Statement

(4) Refer to the [Research Governance Policy](#).

# Section 6 - Procedures

## Part A - Regulatory Environment

(5) Human research is governed by the [National Statement](#). In Victoria, human research also needs to comply with the requirements of state regulators, including Privacy Victoria, the [Department of Health and Human Services](#), the [Department of Education](#), and the [Department of Justice and Community Safety](#). Researchers should consult with the legislation and ethical review requirements of other states and countries when planning to conduct research outside Victoria. La Trobe researchers and research students are also expected to adhere to responsible research practices as established by the [Australian Code for the Responsible Conduct of Research \(2018\)](#).

## Part B - Role of the University Human Research Ethics Review Bodies

(6) In accordance with the [National Statement](#) 5.1.3, La Trobe University ensures that human research under its responsibility meets both the ethical standards and scholarly or scientific standards. It also ensures that human research adequately takes account of consumer and community perspectives ([National Statement](#) 5.1.4).

(7) The primary responsibility of the La Trobe University human research ethics review bodies are to ensure, on behalf of La Trobe, that all activities relating to research involving humans abides by the requirements in the [National Statement](#) and that research proposals are designed in accordance with the following values:

- a. Research merit and integrity
- b. Justice
- c. Beneficence
- d. Respect for human beings

(8) In accordance with the [National Statement](#), La Trobe has established two Human Research Ethics Committees (HRECs) for the review of more than low risk human research and a Low Risk Ethics Advisory Panel (LEAP) for the review of low risk research. Together, these groups are referred to as the ethical review bodies.

(9) The HREC and LEAP review submissions for human research projects and clinical trials and must approve only those submissions that meet an ethically acceptable standard and conform to all the requirements of the [National Statement](#).

(10) Ethics approval must be obtained before starting any human research conducted under the auspices of La Trobe University. Retrospective approval is not permitted, in accordance with [National Statement](#) 5.1.6.

## Part C - Ethical Review Body Terms of Reference

(11) The HREC and LEAP Terms of Reference align with the requirements specified in the National Statement. As a sub-Committee of the Research and Graduate Studies Committee (RGSC) the HRECs and LEAP report on a regular basis to the RGSC. The Terms of Reference are publicly available on the [Human Research Ethics website](#).

## Part D - Standard Applications

(12) The applicant must complete the appropriate ethics submission form and submit with the relevant accompanying and supporting documentation in La Trobe University's PRIME system including, as applicable:

- a. recruitment materials (advertisements, posters, flyers, brochures etc.);
- b. participant information and consent form/s;

- c. research instruments (questionnaire/s, survey/s and/or proposed interview/focus group outline);
- d. other material required as part of the submission process.

(13) For honours, postgraduate, higher degree by research (HDR) and honorary appointees (other than Emeriti) projects, the Supervisor will be named as Principal Investigator on the submission form and is responsible as Principal Investigator. Submissions where the ethics application and conagoth status as Principal Investigator are built into the contract, such individuals will also be able to serve as Principal Investigator.

(14) Submission dates for submissions and meeting dates for the ethics review bodies are published on the [Human Research Ethics website](#). Applications that do not meet relevant submission dates or other governance requirements will be held over to a following meeting.

(15) Meeting agendas are subject to capping dependent upon the volume and complexity of the submissions received. Submissions that are received after a cap has been placed will be prioritised for the next meeting.

(16) Where the submission represents a clinical trial, the [Research Clinical Trials Policy](#) should also be consulted.

(17) The La Trobe University ethics review bodies may approve, request modification of, reject or withdraw approval of a research proposal. If a research proposal receives an outcome other than approval, the ethics review body will provide the rationale underpinning its decision including National Statement, La Trobe University policy and other relevant guidelines, legislation or regulations citations (See [National Statement](#) 5.2.7).

(18) Where a research proposal is approved or rejected, or where approval is withdrawn, the La Trobe University outcome must be in writing (including electronic formats) and will include a clear statement that the proposal meets or did not meet the requirements of the [National Statement](#) (5.2.13(a)).

(19) Researchers will not collect data or commence recruitment activities without first receiving formal notification of ethics approval. Scoping and other pre-research planning activities may proceed prior to approval.

(20) Researchers must also ensure that all relevant and required permissions and permits are secured prior to conducting research.

## **Part E - Aboriginal and Torres Strait Islander Research**

(21) Aboriginal and Torres Strait Islander research includes any research that affects or holds particular significance for Aboriginal and Torres Strait Islander peoples. This includes all stages of the research process—planning, collection, analysis, and dissemination of information or knowledge—regardless of format or medium. It applies whether the research is about, or may impact, Indigenous individuals or communities.

(22) The [Australian Institute of Aboriginal and Torres Strait Islander Studies \(AIATSIS\) Code of Ethics](#) applies to all research involving Aboriginal and Torres Strait Islander peoples. This includes research that does not involve direct human participation, such as the use of archives, datasets, collections of information, or biospecimens that may not otherwise be classified as human research.

(23) Research involving Aboriginal and Torres Strait Islander people and communities should be led and governed by those communities. Meaningful and ongoing engagement is essential to ensure that research priorities are determined and guided by the people and communities involved, and that the research benefits those with whom and for whom the work is being undertaken.

(24) To determine whether a project involves Aboriginal and Torres Strait Islander peoples, researchers should consider whether:

- a. the research addresses a topic identified as a priority or of specific benefit to Aboriginal and Torres Strait

Islander people and communities;

- b. the research cohort includes a significant proportion of Aboriginal and Torres Strait Islander participants (whether through targeted, foreseeable, or incidental recruitment);
- c. the location or recruitment strategy is likely to involve a significant proportion of Aboriginal and Torres Strait Islander people or communities;
- d. the data collected will include analysis that specifically identifies Aboriginal and Torres Strait Islander people and communities;
- e. the outcomes of the research will specifically impact Aboriginal and Torres Strait Islander people and communities.

(25) Researchers must adhere to both the [National Statement](#) and the six core values outlined in the NHMRC's [Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders \(2018\)](#). These six core values are:

- a. Spirit and integrity
- b. Cultural continuity
- c. Equity
- d. Reciprocity
- e. Respect
- f. Responsibility

(26) These core values ensure that research involving Aboriginal and Torres Strait Islander peoples:

- a. respects the diversity of values within these communities;
- b. reflects their priorities, needs, and aspirations;
- c. builds long-term ethical relationships between researchers, institutions, and sponsors;
- d. aligns with best practice ethical research standards.

(27) For the purposes of this Code, Aboriginal and Torres Strait Islander research is defined as research that involves or affects Aboriginal and Torres Strait Islander peoples in any of the following ways:

- a. the research focuses on Aboriginal and Torres Strait Islander peoples, societies, cultures, knowledge, policies, or experiences;
- b. the target population includes Aboriginal and Torres Strait Islander individuals, groups, communities, or societies;
- c. while the target population is not explicitly Aboriginal and Torres Strait Islander, the study includes a significant number of Aboriginal and Torres Strait Islander participants, including incidental recruitment where separate analysis is planned;
- d. Aboriginal and Torres Strait Islander individuals or communities are contributing to the research;
- e. the research uses new or existing data related to Aboriginal and Torres Strait Islander peoples;
- f. the research involves Aboriginal and Torres Strait Islander lands or waters.

(28) Researchers and ethics review bodies must apply the values and ethical guidance from the [National Statement](#) and other key documents, including:

- a. [AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research \(2020\)](#)
- b. A Guide to Applying the [AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research \(2020\)](#)
- c. [Keeping Research on Track II \(2018\)](#)

(29) At La Trobe University, ethical review of research involving Aboriginal and Torres Strait Islander peoples will include assessment by, and/or advice from:

- a. individuals who have established networks with Aboriginal and Torres Strait Islander peoples and/or knowledge of research involving these communities;
- b. individuals familiar with the cultures and practices of the Aboriginal and Torres Strait Islander peoples involved in the research.

(30) Researchers must not begin data collection or participant recruitment until formal ethics approval has been granted. However, pre-research activities such as scoping and planning may proceed prior to approval.

(31) Before conducting research, researchers must also ensure that all necessary permissions and permits are obtained.

## **Part F - Application for Exemption from Ethics Review**

(32) Research that may be eligible for exemption from ethics review includes that which carries a lower risk to the participants or the community and satisfies one or more of the following criteria ([National Statement](#) 5.1.17):

- a. the research involves the use of collections of information or data from which all personal identifiers have been removed prior to being received by the researchers and where researchers explicitly agree:
  - i. not to attempt to re-identify those with whom the information or data is associated;
  - ii. to take all reasonable steps to prevent re-identification of the information or data for unauthorised purposes or access to the information or data by those who are not authorised;
  - iii. that any sharing of any research data during or after the project will not create any additional risks of re-identification of the information or data;
- b. the research is restricted to surveys and observation of public behaviour using information that was or will be collected and recorded without personal identifiers and is highly unlikely to cause distress to anyone associated with the information or the outcomes of the research;
- c. the research is conducted as part of an educational training program in which the research activity is for training purposes only and where any outcomes or documentation are for program use only;
- d. the research uses only information that is publicly available through a mechanism set out by legislation or regulation and that is protected by law, such as mandatory reporting information, information obtained from registries of births and deaths, coronial investigations or reports of the Australian Bureau of Statistics.

(33) Shared or banked data or information that is stored in a form that can identify individuals can sometimes be used in research that qualifies as lower risk research; however, it cannot be used in research that is exempt from ethics review.

(34) The submission process for exemption requests is published on the [Human Research Ethics website](#).

## **Part G - Registering or Transferring an Externally Approved Project**

(35) The [National Statement](#) stipulates that institutions have a responsibility to adopt a process that eliminates any unnecessary duplication of ethical review. Accordingly, La Trobe University accepts human ethics approvals from other human research ethics committees registered with the National Health and Medical Research Council (NHMRC). Research approved by another HREC where La Trobe University researchers are involved must be registered via the externally approved projects pathway. This process is available on the [Human Research Ethics website](#).

(36) The review is conducted by the relevant review body chair (or delegate), based on the level of risk. In accordance

with [National Statement](#) 5.1.38, La Trobe University ensures that its ethics review bodies have access to the expertise necessary to enable them to properly review the research that they consider. This may necessitate going outside of the review body's membership for review of individual research projects. La Trobe University reserves the right to place conditions on involvement or refuse involvement in research should externally approved proposals not conform to the requirements of the [National Statement](#) and other relevant legislation or potentially expose the University to undue risk.

## Part H - Post Approval Requirements

(37) Annual Progress Reports: The Principal Investigator (Principal Investigator) of a La Trobe University human research ethics approved project must submit an Annual Progress Report to the La Trobe University research ethics review body as a condition of project approval. Principal Investigators who fail to submit a Progress Report by the due date may have their project suspended until a report has been received and reviewed by the La Trobe University ethics review body. New project submissions will not be accepted from a researcher with outstanding reports.

(38) Annual Safety Reports for clinical trials: It is a requirement that Principal Investigators or sponsors of clinical trials must submit an Annual Safety Report which will be reviewed by the human research ethics body (or delegate) to assess whether ongoing safety monitoring is being conducted appropriately and that the trial's safety monitoring plans are being followed and where necessary, are being adapted to take into account new findings as the trial progresses.

(39) The Principal Investigator of a La Trobe University human research ethics approved project is required to submit a Request for Modification in PRIME if they intend to modify their approved project. All modification requests must be submitted and approved prior to the implementation of such changes. The request for modification must be accompanied by a track changed version of the original approved protocol with the proposed modification and a clean copy of the modified protocol. Modifications to La Trobe University human research ethics approved projects can only be granted if there is no significant change to the direction of the study. Modifications may include:

- a. a change in participant numbers, recruitment methods, or consent process;
- b. a change to or addition of procedures or techniques;
- c. the addition or removal of investigators, including the Principal Investigator, Primary Supervisor or HDR candidate;
- d. a reasonable extension of the study duration. Extensions will be granted for no more than 12 months at a time. Any extension request beyond 7 years will be considered on a case-by-case basis and researchers may be required to submit a new submission at this time;
- e. an HDR candidate or student taking a leave of absence from their program;
- f. changes to research methodology, sites/location, or data storage;
- g. other administrative changes.

(40) Final Reports: It is a requirement of all La Trobe University human research ethics approved projects that a final report is submitted by the Principal Investigator within three months of the conclusion of the project or within three (3) months of the expiry date whichever is lesser. Final Reports are reviewed by the La Trobe University ethics review body and kept by La Trobe University as an official record from the Principal Investigator regarding the outcome of human participation during the approval period. New project submissions will not be accepted from a researcher with outstanding reports.

(41) In line with [National Statement](#) 5.4.2 and 5.4.8 monitoring arrangements should be commensurate with the risk, size and complexity of the research and should occur at regular periods reflecting these. The minimum monitoring is Annual Progress Reports and Annual Safety Reports for clinical trials along with a Final Report at the end of the research. Additional regular periods of reporting may be implemented based on the criteria of risk, size and

complexity of the research with such intervals to be determined by the ethics review body and clearly outlined with reference to the [National Statement](#).

## Part I - Adverse Events, Safety Issues and Breach Events

(42) In keeping with the conditions for ethics approval, the Principal Investigator must notify the La Trobe University ethics review body of any Serious Adverse Events, Significant Safety Issues, data breaches and Serious Breaches of Good Clinical Practice by the completion of an Adverse Event Report via PRIME within 72 hours.

(43) In keeping with the conditions for ethics approvals of clinical trials, the Principal Investigator must notify the La Trobe University ethics review body of Adverse Events (AEs) by the completion of an Adverse Event Report via PRIME within 72 hours or as soon as possible.

(44) Upon review, the La Trobe University ethics review body may appoint an Assessment Officer to collect more information and prepare a Breach Notification Report in accordance with the University Compliance Framework if the AE may be related to potential breach of the [Australian Code for the Responsible Conduct of Research \(2018\)](#).

(45) Adverse Event, Serious Adverse Event, Safety and Breach Notification Reports will be reviewed by the La Trobe University ethics review body Chair (or delegate) and the Senior Manager, Ethics Integrity and Biosafety, actioned accordingly and ratified by the review body at their next meeting.

## Part J - Risk-Based Monitoring

(46) According to the [National Statement](#), monitoring means measures undertaken to assess, or to ensure the assessment of, the wellbeing of participants and their privacy and confidentiality. [National Statement](#) 5.4.1 provides that institutions have the ultimate responsibility for ensuring all its authorised research is monitored via its internal research governance arrangements. La Trobe University research governance arrangements include the Council mandated [Risk Based Monitoring framework](#) which aligns with [National Statement](#) 5.4.3 (v - vii). The La Trobe University Risk-Based Monitoring Framework aligns with the audits and reports outlined in [National Statement](#) 5.4.3 (v)(vi) and (vii).

(47) For human research, the purpose is to ensure that the engagement of human participants in research is conducted in compliance with the [National Statement](#) and other relevant national guidelines, and in accordance with La Trobe University human research ethics body approval. The system is based on an established set of criteria outlined in the La Trobe University [Risk Based Monitoring framework](#). Monitoring will depend on the degree of risk that arises from the research and should be proportionate to that risk.

(48) Risk-based monitoring is a joint responsibility between La Trobe University human research ethics review bodies and Ethics, Integrity and Biosafety to ensure research is conducted in compliance with the relevant approval/s and regulatory requirements.

(49) Risk-based monitoring visits will be conducted in partnership with the researchers. Prior to project monitoring, the purpose and process will be clearly communicated to the researchers. It is also an opportunity for the researchers to meet members of the La Trobe University human research ethics review bodies, share their work and ask questions.

(50) Risk-based monitoring will be defined on a case-by-case basis and may include:

- a. pre-monitoring review of all relevant documentation in PRIME by the Ethics, Integrity and Biosafety team prior to the monitoring visit;
- b. monitoring visit:
  - i. face-to-face visits (in-person or remote) can include a meeting with the project Principal Investigator and relevant co-investigators;

- ii. remote meetings including records off-site records access and review;
  - iii. for-cause visits can be arranged to address unanticipated issues that arise which require remediation. These will only be conducted on an as-needed basis;
  - iv. close-out visit, if required, to confirm recommended actions have been completed.
- c. Focused monitoring will be conducted where areas of a project have been identified to carry higher risk such as management of conflicts of interest.

(51) Risk-based monitoring activities and recommended actions will be documented and communicated to the Principal Investigator.

(52) Results of risk-based monitoring including recommendations for preventative and corrective actions will be prepared by the Ethics, Integrity and Biosafety team, with appropriate consultation with the review body, where required. The Ethics, Integrity and Biosafety team will ensure these actions are appropriately followed up and actioned.

(53) Findings from a pre-monitoring review or risk-based monitoring that indicate a breach of the Code, including evidence of research conducted without ethics approval, will be appropriately referred under the [La Trobe University Research Misconduct Procedure](#).

## **Part K - Departure of a Principal Investigator**

(54) If the Principal Investigator of an active approved human research ethics approved project plans to leave the University or transfer to another organisation, the Principal Investigator must notify the Ethics, Integrity and Biosafety (Ethics, Integrity and Biosafety) team prior to their departure. The Principal Investigator has the option to:

- a. nominate a different La Trobe University staff member as the new Principal Investigator through a modification request to the La Trobe University human research ethics body;
- b. request a transfer through the new institution's Ethics Office. The La Trobe University human research ethics Secretariat will facilitate by providing records to the new Ethics Office;
- c. provide a final report closing the project.

(55) Failure to complete this step may result in a report of potential research misconduct.

## **Part L - Complaints**

(56) Anyone interested in voicing a concern or lodging a complaint regarding the conduct of a human research project, including clinical trials, is encouraged to do so in writing by emailing the Senior Manager Ethics, Integrity and Biosafety at [eib@latrobe.edu.au](mailto:eib@latrobe.edu.au). The human research ethics complaints process can be found on the [Human Research Ethics website](#).

(57) In accordance with [National Statement](#) 5.7.3, researchers have the right to express concerns regarding the ethical review process. Researchers are encouraged to address concerns with the ethics review body in the first instance. If the concern cannot be resolved through direct communication, a written complaint may be submitted to the Senior Manager, Ethics Integrity and Biosafety at [eib@latrobe.edu.au](mailto:eib@latrobe.edu.au) who will inform the review body of the complaint and seek to resolve the issue. The process is available on the [Human Research Ethics website](#). La Trobe University may choose to refer the complaint to an assessor who is independent of the University and the ethics review body.

(58) Any unplanned impacts on human research participants or researchers outside the scope of the La Trobe University human research ethics review bodies must be reported promptly to the Senior Manager, Ethics Integrity and Biosafety.

(59) Concerns or complaints regarding potential research misconduct, including evidence of human research conducted without ethics approval, or when an investigation or review indicates that an issue may also involve a breach or a potential breach of the [Australian Code for the Responsible Conduct of Research \(2018\)](#), will be referred under the La Trobe University [Research Misconduct Procedure](#).

## Section 7 - Definitions

(60) For the purpose of this Procedure:

- a. Adverse Event: any unfavourable medical occurrence—such as a symptom, disease, or abnormal lab finding—that happens to a research participant during the study, regardless of whether it is caused by the research itself. Adverse events can be physical, psychological, or social, and can range from minor inconveniences to serious outcomes like death, hospitalisation, or long-term disability.
- b. Compliance: acting in accordance with the National Statement and other relevant regulations and legislation.
- c. Discomfort: a negative accompaniment or effect of research, less serious than harm.
- d. Ethics: a framework in which actions can be considered as good or bad, right or wrong. Ethics is applied in the evaluation of what should or should not be done when human beings are involved in research.
- e. Incident: an event that impacts a project and/or participants that is not associated with a clinical trial, including but not limited to, a safety issue or departure from an ethically approved project description.
- f. Low risk research: research in which the only foreseeable risk is one of discomfort.
- g. Principal Investigator: refers to the researcher primarily responsible for the conduct of the research.
- h. Research Monitoring: monitoring of research refers to the process of verifying that the research is conducted in accordance with the Australian Code for the Responsible Conduct of Research (2018), relevant state and federal legislation and applicable ethical and biosafety approvals.
- i. Safety Report: a formal document summarising new or important safety information about a medical product, including adverse events and potential risks to participants. Its primary purpose is to ensure patient safety and the ethical conduct of the trial by providing an early warning system for potential safety issues.
- j. Serious Adverse Event: any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.
- k. Serious Breach: a breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree the safety or rights of a trial participant, or the reliability and robustness of the data generated in the clinical trial.
- l. Significant Safety Issue: a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

## Section 8 - Authority and Associated Information

(61) This Policy is made under the [La Trobe University Act 2009](#).

## Status and Details

<b>Status</b>	Current
<b>Effective Date</b>	4th December 2025
<b>Review Date</b>	19th November 2028
<b>Approval Authority</b>	Academic Board
<b>Approval Date</b>	4th December 2025
<b>Expiry Date</b>	Not Applicable
<b>Responsible Manager - Policy</b>	Alistair Duncan Executive Director, Research Office
<b>Enquiries Contact</b>	Ethics, Integrity and Biosafety

## Glossary Terms and Definitions

**"CONAGOTH"** - Consultants, Agency or Other