

Research Governance Policy

Section 1 - Background and Purpose

- (1) The academic and research community is dependent on public trust in the quality and safety of the research they produce.
- (2) The statutory purpose of La Trobe University is 'to undertake scholarship, pure and applied research, invention, innovation, education and consultancy of international standing and to apply those matters to the advancement of knowledge and to the benefit of the well-being of the Victorian, Australian and international communities'. It also seeks to meet the goals of the operational strategic research plan to grow its research and increase research impact. These goals include becoming recognised as the 'unrivalled partner of choice'.
- (3) The University has also established a set of cultural qualities reflecting the commitment of the University to be accountable, to be connected to the world outside the University, to be innovative and to care about what we do and why we do it.
- (4) To support these goals this Policy establishes a [Research Governance Framework](#) (The Framework) to enable researchers and their associates to understand their obligations and to meet the expectations of the University and the community.
- (5) Research governance is defined as the accountabilities and processes in place to ensure high quality research that meets legislative and regulatory requirements, policy mandates, principles and best practice standards.
- (6) The Framework provides guidance to ensure relevant regulations, principles and standards are met. It also outlines who is responsible and accountable during the research lifecycle and acknowledges the role of researchers and research staff in maintaining a culture of excellence, and provides partners, including clinical partners, with clear view of La Trobe's research governance.
- (7) The Framework seeks to ensure researchers and the University are compliant with the [Australian Code for the Responsible Conduct of Research \(2018\)](#) (the Code).
- (8) The purpose of the Policy is to:
- Create a culture that is committed to delivering high quality and ethically sound research that is conducted with integrity;
 - Ensure all researchers are clear about their roles and responsibilities;
 - Ensure all University officers and support units are clear about their roles and responsibilities;
 - Provide clear pathways for researchers to meet their obligations;
 - Promote the collaborative nature of research;
 - Promote excellence in external research partnerships;
 - Ensure all legislative and regulatory requirements are met;
 - Deliver a high level of transparency and accountability for all research; and
 - Ensure appropriate oversight, monitoring and review of research governance.

Section 2 - Scope

(9) This Policy applies to all members of the University community as defined in the University [Code of Conduct](#), and includes student researchers. Collaborators are expected to be made aware of and demonstrate compliance with the Policy.

Section 3 - Policy Statement

(10) This Policy is based on the following Principles of Research Governance:

- a. Research Integrity: Research will be conducted with the highest levels of research integrity, enabling the public and research community to have trust and confidence in the research and its results. All those engaged in research, including students, must abide by all relevant guidelines and legislative and regulatory requirements.
- b. Research Quality: Research should be of the highest ethical, scientific and scholarly standards, contributing to the advancement of knowledge. It should be translated, when appropriate, into relevant policies and practice and provide impact beyond the University that meets the needs of our community and stakeholders.
- c. Ethics and Biosafety Review: All research will be ethical and compliant with any ethics and biosafety review required of that research.
- d. Quality Collaboration and Partnerships: Those undertaking research activities will work to ensure effective and transparent collaboration among internal and external stakeholders, including national and international partners. This includes creating clear, mutually beneficial and effective partnership arrangements.
- e. Community Engagement and Protection: Those undertaking research involving humans will have a participant centred approach that involves meaningful engagement with, respect for and protection of participants' rights.
- f. Accountability and Transparency: Those conducting research will take responsibility and be accountable for their behaviour and actions. All research activity will be open to review and all findings and data will be made publicly available where possible.
- g. Qualified Personnel: All those conducting research should be appropriately qualified and experienced and conduct their research with due regard to the safety of themselves, their colleagues and collaborators and any participants in their research, including animals and the environment.
- h. Risk Management: Researchers and the University are to manage the risks associated with research projects. This includes financial, legal, insurance and reputational risks so as to protect researchers, participants, the University and research partners.
- i. Monitoring and Review: Research processes at the University will be monitored and areas of risk for researchers or the University reviewed as part of the University's Governance responsibility.

(11) All members of the University have responsibility for meeting the requirements of this Policy. Details of specific research governance responsibilities and roles in reviewing, approving, managing and monitoring research are provided in the relevant Policies and Procedures and are summarised in Section 6.

Section 4 - Procedures

Part A - Research Integrity

(12) All Researchers must comply with the [Research Integrity Policy](#) and the [Research Misconduct Procedure](#), the [Research - Higher Degree Student Misconduct Procedure](#), the [Research Clinical Trials Policy](#) and the [Conflict of Interest Policy](#). The [Conflict of Interest Policy](#) applies to all staff and students and therefore encompasses research activity.

(13) All researchers, including students undertaking research, must conduct themselves in a manner that supports the

University [Code of Conduct](#) as well as complying with their conditions of employment or student registration. All members of the University research community have a responsibility to ensure that any research is conducted in accordance with relevant Federal and State legislation and regulations.

(14) Students undertaking research in any higher degree, and their supervisors, must be aware of their responsibilities, as outlined in the [Research - Higher Degree Student Misconduct Procedure](#), to ensure research is conducted in accordance with the [Code](#) and the [Research Integrity Policy](#). Supervisors of students undertaking a higher degree by research will ensure that they meet the responsibilities outlined in the [Graduate Research Supervision Policy](#) and that students under their supervision receive appropriate guidance and training.

(15) The [Research Integrity Policy](#) requires researchers to read and comply with Procedures that relate to research regulation, specifically:

- a. [Research Animal Ethics Procedure](#);
- b. [Research Biosafety and Biosecurity Procedure](#); and
- c. [Research Human Ethics Procedure](#).

(16) All Australian Institutions undertaking research are responsible for ensuring that any research they conduct is in accordance with the [Code](#) and ethically approved and monitored in accordance with the guidance of the [National Statement on Ethical Conduct in Human Research 2023](#) (National Statement) and the [Australian code for the care and use of animals for scientific purposes](#).

(17) Researchers must ensure they act in a manner consistent with the University's [Protection of Freedom of Speech and Academic Freedom Policy](#).

Part B - Research Quality

(18) All research should be carried out in a manner that aims for the highest quality of ethical, scientific and scholarly outcomes. Internal and external peer review are the traditional means of objectively assessing whether the design of a study is optimal and all researchers are expected to follow the University's [Research Peer Review Procedure](#).

(19) The University recognises that the objectives and design for undergraduate and postgraduate research are part of a learning experience and need to be assessed in that light. All research should be designed and conducted in a manner that aims to make a meaningful contribution to knowledge and improve outcomes for the community and provide research impact beyond the University.

(20) The University requires researchers to obtain input from relevant research peers for any research, including, where appropriate:

- a. Engagement with relevant consumers and stakeholders of the research, employing key methodologies such as co-design;
- b. Statistical evaluation to ensure that any study involving statistical methodologies will achieve its objectives and has an appropriate data collection and analysis plan; and
- c. Review by experts in ethical and regulatory matters with official review and approval by the relevant ethical and biosafety review bodies, where appropriate, to ensure that the research maintains community standards.

(21) All research is to be carefully managed to ensure that it is delivered safely, effectively and in a cost-effective manner.

(22) All research should wherever possible align with the University Research Strategy.

Part C - Ethical Review

Animal Research

(23) Where animals are used in research projects, all research must be reviewed and approved by the La Trobe Animal Ethics Committee. Researchers should make themselves aware of all the requirements set out in the [Australian code for the care and use of animals for scientific purposes](#) and to apply this in designing their projects and in their submission to the Animal Ethics Committee.

Biosafety and Biosecurity

(24) Governance and oversight for the management of biosafety and/or biosecurity risks associated with the University's biological research and teaching activities are outlined in the [Research Biosafety and Biosecurity Policy](#) and [Research Biosafety and Biosecurity Procedure](#).

(25) All research projects involving gene technology and the use of hazardous organisms must be assessed by the La Trobe Institutional Biosafety Committee (LTIBC). The LTIBC will assist researchers to adhere to and comply with the principles of research integrity, relevant biosafety and biosecurity legislation (the [Gene Technology Act 2000](#) and the [Gene Technology Regulations 2001](#); the [Biosecurity Act 2015](#)); [National Framework of Ethical Principles in Gene Technology 2012](#) and other regulatory requirements. This includes ensuring projects and research facilities are appropriately classified in accordance with the relevant regulations and that any actual or potential risks to the health and safety of people and the environment are identified and managed. All those involved with laboratory based research must comply with the [Health and Safety Procedure - Laboratory \(Research\) Safety](#).

Human Research

(26) Institutions that conduct research involving humans must comply with the [National Statement](#) as described in the [Research Human Ethics Procedure](#). All research involving humans requires review by a National Health and Medical Research Council registered Human Research Ethics Committee (HREC). The University HREC will review most research that originates from within the university itself.

(27) For research involving external health services, both public and private, researchers must seek advice from the Ethics, Integrity and Biosafety team on the most appropriate HREC. Consistent with section 5.3.1 of the [National Statement](#), the University may accept the review of an external HREC by agreement.

(28) Research involving Aboriginal and Torres Strait Islander peoples and communities need to comply with the [Ethical Conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders](#), [Keeping Research on Track II](#), and the [Australian Institute of Aboriginal and Torres Strait Islander Studies \(AIATSIS\) Code of Ethics for Aboriginal and Torres Strait Islander Research](#).

Quality Collaboration and Partnerships

(29) Researchers are encouraged to collaborate on research projects and activities with external parties. If a research project with external parties is funded, or involves other forms of institutional commitment, ethical or other risks, including potential intellectual property and data sharing, then it should be managed through an appropriate Collaborative Agreement or Contract. In such cases, researchers must consult with the Research Office.

(30) Researchers running clinical trials must adhere to the [Research Clinical Trials Policy](#) and must establish an effective and transparent collaboration agreement with particular emphasis on lines of responsibility and accountability.

Community Engagement and Protection

(31) Being connected is identified as one of the cultural qualities central to the University's strategic plan. Researchers are encouraged to engage with communities external to the University and ensure our research makes a difference by working with our communities and partners, and utilising the research expertise that exists on all our campuses. We will focus on becoming the partner of choice. University researchers are expected to consider the impact of their work on the community and, where possible, to actively engage with the relevant communities and stakeholders in the design, conduct and translation of research outcomes.

Part D - Accountability and Transparency

Research Reporting

(32) The University expects researchers to publish their work wherever possible and abide by the requirement as outlined in the [National Statement](#), the [Australian Privacy Principles](#) and any state and territory legislation as relevant.

(33) Researchers must follow the [Research Authorship and Outputs Policy](#) when attributing authorship for any 'substantial scholarly or intellectual contribution to the research output' to ensure that individuals or organisations that made contributions are appropriately recognised.

Data Management

(34) It is the responsibility of the researcher to ensure the secure management, storage, retention and disposal of research data throughout and after the completion of a research project for the mandated retention periods. Researchers must comply with the University [Research Data Management Policy](#) and [Information Security Policy](#).

(35) Records Management is mandatory and required of all members of the University research community, including contractors and volunteers. Researchers need to comply with the [Records Management Policy](#). Researchers can contact the University Digital Records who manage the University Archives to understand what is required and they can assist with compliance.

(36) All research involving the use of personal information, particularly health information, must abide by the requirements outlined in the Australian Privacy Principles; the [Guardianship and Administration Act 2019](#); the [Health Records Act 2001](#); the [National Statement](#); the [Code](#), and the legislation and regulations of the state or country where the research will take place. In addition, the La Trobe University [Privacy Policy](#) will apply.

Qualified Personnel

(37) All researchers and their associates should be appropriately qualified and sufficiently experienced to ensure they can conduct their research safely and effectively. Records related to appointments and scope of practice should be kept and monitored in alignment with the [Recruitment Policy](#) and the [Direct Appointment Policy](#).

(38) The University is committed to providing pathways for research to be a core part of undergraduate and postgraduate learning. In all cases student research projects must be supervised by an appropriately qualified staff member who must not be a student and who is responsible and accountable for that project.

(39) All researchers, whether staff or students or otherwise, are required to be familiar with the Policies and Procedures relevant to their research.

(40) The Ethics, Integrity and Biosafety team and the Research Education and Development (RED) unit provide training and information resources for ethical, biosafety and regulatory compliance, and are available for all researchers and research students at the University.

Part E - Risk Management

(41) Research should be managed within the context of the overarching University [Risk Management Policy](#) which describes risk management as a core component of Corporate Governance. Risk management is governed by the University Risk Appetite Statement which defines the level of acceptable risk taking. Researchers and the University are to manage the risks associated with research projects.

(42) Where projects require contracts or agreements with external parties or collaborators, they must have appropriate legal review to protect researchers, research participants, and the University. Research must be financially well managed to ensure transparency and accurate financial reporting. All members of the University need to comply with the University [Risk Management Policy](#) and the [Compliance Management Policy](#).

Research Agreements and Contracts Review

(43) The type of research activity and nature of the relationship between collaborating parties will determine the most appropriate contractual agreement. Because the nature of these agreements can vary greatly, researchers should discuss their projects with the Research Office for advice and to ensure that the correct documentation is used. Legal review of Research Agreements may be required for any agreement. Researchers cannot sign legal agreements or research contracts. These can only be signed by an authorised signing authority as listed for research agreements in the [Instruments of Delegation](#).

(44) All funded research projects must ensure high quality financial management, including in the initial costing and budget and must be transparent and accountable. Researchers must be aware of the financial obligations of their projects. The University Research Office provides support for researchers, through the Research Grants Development and Transformation team and the Consulting and Contracts team, for developing and submitting funding applications, for planning budgets and for managing funding and consultancy agreements. External funding is managed under the [Research Contracts and Grants Policy](#) and all researchers must read and comply with this.

Insurance and Indemnity

(45) The University must be satisfied that all research is covered by adequate insurance arrangements in accordance with applicable regulatory requirements. The University has robust insurance policies in place to protect the University, employees and students. The type of insurance coverage available is dependent on the nature of activities, however public liability is largely provided, pending the research and activities being undertaken are at the bequest of and on behalf of the University. Specialist insurance, such as Clinical Trials, is also available, subject to terms and exclusions. Valid insurance cover requires all staff and students to comply with relevant policies and regulations and does not extend to cover any malicious or unlawful activities. Please contact the insurance office for tailored advice and information.

(46) Documentation of appropriate levels of insurance and indemnification must be provided by any third parties that University staff and students engage with in their research. The University's insurance does not extend to covering a third party's liability.

Protection of Intellectual Property

(47) Researchers need to be aware of their responsibilities and obligations over intellectual property, including ownership, copyright and patents. The potential to generate intellectual property means that the University, external collaborators or the researchers themselves may have an interest. The University policy is designed to ensure commercially valuable Intellectual Property is protected to the benefit of relevant parties and society. All University researchers must ensure that they comply with the [Intellectual Property Policy](#).

Other Risks

(48) Researchers need to comply with the [Autonomous Sanctions Policy](#) to ensure the University is in compliance with the United Nations Security Council (UNSC) sanctions regimes and Autonomous Sanctions regime.

Part F - Monitoring and Review

(49) Researchers and the University have an obligation to monitor the progress, integrity and compliance of research projects in compliance with this Policy. The University will review any existing or emerging risks for researchers or the University as part of its Governance responsibility. The University has a research governance monitoring and audit program that is managed by the Ethics, Integrity and Biosafety team.

University Research Monitoring

(50) Both the [Code](#) and [National Statement](#) outline the necessity for monitoring of research to ensure that the research is being conducted in accordance with any regulatory approvals or contracts. Mechanisms for monitoring include:

- a. Reports from researchers;
- b. Reports from independent agencies (such as data and safety monitoring boards);
- c. Spontaneous and regular inspection of research sites, data or consent documentation; and
- d. interviews with researchers, participants or other forms of feedback.

(51) The frequency and type of monitoring will depend on the degree of risk that arises from the research and should be proportionate to that risk. All research should be monitored for compliance with the University's policies and procedures and relevant guidelines and legislation. The Research Office must ensure systems are in place for the management of complaints, including research misconduct and fraud. All levels of the University Community who are active in research have an obligation to be aware of integrity requirements and to report potential breaches to the Senior Manager, Ethics, Integrity and Biosafety.

Section 5 - Definitions

(52) For the purpose of this Policy and Procedure:

- a. Clinical trial: refers to any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.
- b. Research: has the definition given in the [Code](#), which states 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.
- c. Researcher: has the meaning given in the [Code](#), which is the person or persons who conducts, or assists with the conduct of research.
- d. Research governance: refers to the processes used by institutions to ensure that relevant standards, principles and regulations are met and that they are accountable for the research conducted under their auspices.
- e. Research Integrity: refers to the values and principles of honesty, objectivity, duty of care, fairness, accuracy and good stewardship of research.
- f. Research Office: refers to the University Unit responsible for managing the University's research portfolio and includes the following teams: Ethics, Integrity and Biosafety; Consulting and Contracts; Research Grant Development and Transformation; and Research Performance.

- g. The Code: refers to the [Code](#) which sets out the principles and responsibilities that both researchers and institutions are expected to follow when conducting research.
- h. The National Statement: refers to the [National Statement](#) and provides guidance to researchers and institutions on best ethical practice when research involves any involvement of people, including observation, engagement, their bodies, ideas or beliefs.
- i. Staff: means all employees of the University or affiliated enterprises with which the University has a formal agreement and includes casual employees, clinical staff and unpaid members of the University such as Honorary and Adjunct appointments, all of which are registered on the Human Resources system.
- j. Student: a student enrolled at the University.

Section 6 - Related Documents

(53) Please refer to the key components of the [Research Governance Framework](#).

Status and Details

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Effective Date	27th April 2023
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Responsible Manager - Policy	Alistair Duncan Executive Director, Research Office
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