Research Biosafety and Biosecurity Policy

Section 1 - Key Information

Policy Type and Approval Body	Academic – Academic Board
Accountable Executive – Policy	Executive Director, Research Strategy & Operations
Responsible Manager – Policy	Senior Manager, Ethics Integrity and Biosafety
Review Date	6 August 2027

Section 2 - Purpose

(1) The purpose of this Policy is to inform all staff, students, visitors and contractors of the University, La Trobe's commitment to providing governance and oversight in effectively managing the actual and potential biosafety and/or biosecurity risks associated with the University's biological research and teaching activities to:

a. ensure the health and safety of university personnel, the community and the environment;
b. promote best practices in research and teaching;
c. ensure adherence and compliance with the principles of research integrity, relevant biosafety and biosecurity legislation, and other regulatory requirements (listed under the associated information page).

(2) The La Trobe Institutional Biosafety Committee (LTIBC) acts as the University's lead governance and advisory body on all matters pertaining to biosafety and biosecurity. This includes:

a. providing advice on the identification and management of the actual and potential risks associated with dealings involving Genetically Modified Organisms (GMOs) and work involving other biological agents or material that pose a risk to the health and safety of personnel, community and the environment;
b. providing guidance on the containment of biological agents and material;
c. monitoring research and teaching activities to ensure compliance with approved dealings and relevant regulatory schemes; and
d. acting as an interface with relevant regulatory agencies that administer, for example, the Gene Technology Act 2000, the Biosecurity Act 2015, the National Health Security Act 2007, the Customs Act 1901 and the Defence Trade Controls Act 2012.

(3) This Policy establishes the framework for how the LTIBC will arrange its processes and services to oversee the biosafety and biosecurity compliance obligations applicable to the University's biological research and teaching activities.

This policy document may be varied, withdrawn or replaced at any time. Printed copies, or part thereof, are regarded as uncontrolled and should not be relied upon as the current version. It is the responsibility of the individual reading this document to always refer to La Trobe's Policy Library for the latest version.

Section 3 - Scope

(4) This Policy applies to:

a. All University campuses, research and teaching areas;
b. All University staff, students, contractors and visitors to the university.

(5) This Policy will be applicable to La Trobe University staff and students undertaking any teaching or research activities on behalf of the University in an out-of-campus premises or site (for example, another institution, fieldwork) within Australia or outside of Australia, unless it is in direct contravention of a local requirement.

Section 4 - Key Decisions

Key Decisions	Role
Reviewing and approving applications for proposed work with regulated biological agents.	La Trobe Institutional Biosafety Committee (LTIBC)
Inspecting certified facilities and managing certification applications.	LTIBC Senior Manager, Ethics Integrity and Biosafety
Managing new facility certifications and facility audits.	LTIBC Senior Coordinator, Research Governance and Operations
Investigating, reporting on and acting on suspected non-compliances and breaches of containment.	LTIBC Senior Manager, Ethics Integrity and Biosafety

Section 5 - Policy Statement

(6) La Trobe University is committed to providing governance and oversight for the management of biosafety and/or biosecurity risks associated with the University's biological research and teaching activities. This is achieved by:

a. Ensuring compliance to the Australian Code for the Responsible Conduct of Research (2018).
b. Ensuring compliance to all applicable legislative and regulatory requirements mentioned under the associated information page.
c. Establishing and implementing a comprehensive biological risk assessment and risk management process.
d. Establishing and implementing a biosafety and biosecurity training program.
e. Identifying the responsible and accountable people at all applicable levels of the University and (if necessary) providing training to them on how to carry out the biosafety and biosecurity responsibilities required of them.
f. Establishing effective and timely communication whereby relevant and up-to-date information is disseminated to and obtained from all identified responsible and accountable people.
g. Undertaking regular inspections and/or audits of all spaces where biological research and teaching activities will be undertaken.
h. Establishing a procedure for identifying, investigating and addressing any non-compliances, breaches and/or misconducts related to biosafety and biosecurity matters.
i. Undertaking regular reviews of the overall biosafety and biosecurity program to ensure that the aims established by this Policy are being met with.

This policy document may be varied, withdrawn or replaced at any time. Printed copies, or part thereof, are regarded as uncontrolled and should not be relied upon as the current version. It is the responsibility of the individual reading this document to always refer to La Trobe's Policy Library for the latest version.

Section 6 - Procedures

(7) Refer to Research Biosafety and Biosecurity Procedure.

Section 7 - Definitions

(8) For the purpose of this Policy:

a. Biosafety: Containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release into the environment.
b. Biological agents: any living organism that may cause harm to people, animals or the environment. This includes pathogens; biological toxins; material of human origin such as blood, body fluids, tissues, cells, cell lines; live animals; material of animal origin such as blood, body fluids, tissues, cells, cell lines; whole plants; plant material; environmental, food and other types of samples that have a potential for containing biological agents including pathogens; any other material of biological origin; and biological molecules such as DNA, RNA extracted from any of the samples mentioned above.
c. Biosecurity: Institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of biological agents that may cause harm to the economy or environment.
d. Biological research and teaching activities: Research and teaching activities that involve working with biological agents.
e. Compliance: The outcome of an organisation meeting its statutory and regulatory obligations (as defined in the University's Compliance Management Policy), and the actions of all personnel, according to their role within the University, conforming to all applicable laws and regulations.
f. Containment: The combination of buildings, engineering function, equipment, and worker practices used to prevent the unintentional release of, or exposure to, a biological agent.
g. Dealings: deal with, in relation to a GMO, means the following:
    i. conduct experiments with the GMO;
    ii. make, develop, produce or manufacture the GMO;
    iii. breed the GMO;
    iv. propagate the GMO;
    v. use the GMO in the course of manufacture of a thing that is not the GMO;
    vi. grow, raise or culture the GMO;
    vii. import the GMO;
    viii. transport the GMO;
    ix. dispose of the GMO; and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing.
h. Genetically Modified Organism (GMO): An organism that has been modified by gene technology; or an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms.
i. Governance: The processes by which the University is directed, controlled and held to account. It encompasses authority, accountability, stewardship, leadership, direction and control exercised in the organisation.
j. Institutional Biosafety Committee: A committee established as an Institutional Biosafety Committee in accordance with written guidelines issued by the Office of Gene Technology Regulator (OGTR) under section 98 of the Gene Technology Act 2000. An Institutional biosafety committee assists organisations by advising on the

identification and management of the risks associated with dealings with GMOs undertaken by the organisation, including the containment of GMOs and providing an interface with the OGTR.

Section 8 - Authority and Associated Information

(9) This Policy is made under the La Trobe University Act 2009.

Status and Details

Status	Current
Effective Date	2nd September 2021
Review Date	6th August 2027
Approval Authority	Academic Board
Approval Date	11th August 2021
Expiry Date	Not Applicable
Responsible Manager - Policy	Mark Li Senior Manager, Ethics Integrity and Biosafety
Enquiries Contact	Ethics, Integrity and Biosafety

Glossary Terms and Definitions

"student" - Student is defined in the La Trobe University Act 2009 as: (a) a person enrolled at the University in a course leading to a degree or other award; or (b) a person who is designated as a student or is of a class of persons designated as students by the Council.

"staff" - Staff means any person employed by the University as per the definition in the La Trobe University Act 2009 (Vic).

This policy document may be varied, withdrawn or replaced at any time. Printed copies, or part thereof, are regarded as uncontrolled and should not be relied upon as the current version. It is the responsibility of the individual reading this document to always refer to La Trobe's Policy Library for the latest version.