Research Biosafety and Biosecurity Procedure

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	27 July 2026

Section 2 - Purpose

(1) La Trobe University is committed to the health and safety of staff and students, the community and the environment. All personnel who intend to conduct research or teaching activities that involve the use of biological material must consider the risks associated with the work and, where applicable, seek guidance and approval from the La Trobe Institutional Biosafety Committee (LTIBC).

(2) The purpose of this procedure is to inform all staff, students, visitors and contractors of their responsibilities with respect to biosafety and biosecurity arising from their teaching, research and services activities.

(3) This procedure is in accordance with the La Trobe Research Biosafety and Biosecurity Policy, a 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. Specifically:

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

(4) This procedure provides information to assist personnel with maintaining compliance with relevant biosafety legislation. The procedure sets the framework and expectations of personnel that may deal with biological materials or agents in their research or for the purposes of teaching. It also provides processes that will assist personnel and the LTIBC in identifying and assessing the risks associated with their work as well as ensuring adherence to legislative requirements.

(5) This procedure provides personnel undertaking activities with biological agents the framework, methodology, processes and approvals to ensure persons:

a. know and understand their obligations;
b. are able to comply with relevant legislation and university policies and procedures; and
c. undertake activities within a best practice and compliant framework.

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(6) This is achieved through:

a. providing simple and clear objectives and responsibilities;
b. high quality engagement between the LTIBC and LTU personnel;
c. effective knowledge transfer through training and guidance;
d. practical solutions to deliver innovative and efficient solutions that are compliant with all regulatory bodies;
e. monitoring research and teaching activities to ensure compliance with approved dealings and relevant regulatory schemes;
f. procedural fairness and continuous improvement by encouraging and fostering a good compliance culture within La Trobe University; and
g. processes and procedures for dealing with non-compliance.

Section 3 - Scope

(7) This Procedure applies to:

a. all staff, students, visitors and contractors with respect to biosafety and biosecurity arising from, their teaching, research or services activities.

Section 4 - Key Decisions

Key Decisions	Role
Reviewing and approving applications for proposed work with regulated biological agents	LTIBC

Section 5 - Policy Statement

(8) This procedure forms part of the Research Biosafety and Biosecurity Policy which governs its application

Section 6 - Procedures

Part A - Governance and Oversight

(9) The Senior Deputy Vice-Chancellor and Vice President (Research and Industry Engagement) (SDVCRIE) is responsible for the development, compliance monitoring and review of this procedure and any associated guidelines. The Research and Graduate Studies Committee (RGSC) review and approve all policies and procedures including any changes identified during formal review.

(10) The Senior Manager, Ethics Integrity and Biosafety (or their nominee) through the Research Office is responsible for the implementation of this procedure in accordance with the scope outlined above. Enquiries about interpretation of this procedure should be directed to the Senior Manager, Ethics Integrity and Biosafety.

(11) The 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 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;

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b. providing guidance on the containment of biological agents and material;
c. 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;
d. conducting annual inspection of certified Physical Containment Facilities to ensure they comply with the certification requirements;
e. conducting internal audits of approved projects to ensure compliance with the Biosafety and Biosecurity Policy and the Biosafety and Biosecurity Procedure; and
f. providing guidance on biosafety and containment of GMOs and the remediation of non-conformity to regulatory requirements.

(12) Facility managers are responsible for:

a. ensuring that personnel and visitors are aware of their responsibilities under this procedure;
b. ensuring that their facilities comply with the requirements of the conditions of the relevant certifications;
c. ensuring transport, storage and disposal of GMOs and other biological material complies with the relevant regulations and guidelines;
d. ensuring that professional staff and contractors are aware of the University's procedures and practices in biological risk management and containment;
e. participating in the internal inspection or audit processes by the LTIBC; and
f. raising any issues of non-conformity, non-compliance or breach with the LTIBC immediately.

(13) Research personnel, students and visitors are responsible for:

a. ensuring that all work involving GMOs has prior approval by the LTIBC and that the work remains compliant and within the scope of approval;
b. discussing with the relevant facility manager and reporting any intended use of GMOs to ensure any actual or potential risks are identified and managed and that all necessary approvals are in place prior to use;
c. reporting to the LTIBC any intended use of GMOs;
d. contributing to School action plans in response to internal audits and reviews as required;
e. completing all necessary biosafety induction and training;
f. carrying out research in accordance with the University's Biosafety Policy and Procedures and all other relevant legislation; and
g. reporting any incidents to the relevant research supervisor(s), manager(s)and/or the Ethics, Integrity and Biosafety (EIB) team.

Part B - Approvals for Working with GMOs

(14) All processes and activities involving gene technology are regulated in Australia through the Gene Technology Act 2000 ('the Act') and the Gene Technology Regulations 2001. In accordance with this legislation, governance and oversight of gene technology at La Trobe is provided by the LTIBC. This applies to all research containing, or potentially containing, hazardous organisms including gene technology research by La Trobe University full time, part time, casual or adjunct staff, students and visitors at all campuses in Australia.

(15) Under 'the Act', La Trobe is an accredited organisation and the LTIBC is an authorised committee in accordance with written guidelines issued by the Regulator under Section 98 of the Act. Responsibilities and operation of the committee are outlined in the LTIBC Terms of Reference and LTIBC Governance and Operation Procedures.

(16) GMO dealings are classified based on the level of risk to the researcher, community and environment. The level of

regulatory scrutiny is proportional to the level of risk. At La Trobe, all classes of dealings must be reviewed by the LTIBC prior to commencement. The three main classes of dealings are: Exempt Dealings, Notifiable Low Risk Dealings (NLRD) and Licensed Dealings (Dealing Not involving an Intentional Release (DNIR) of GMOs into the environment; or Dealing involving an Intentional Release (DIR) of GMOs into the environment).

(17) Detailed descriptions of each class and corresponding application forms are available on the EIB website.

(18) Researchers wishing to conduct dealings should:

a. refer to the EIB website;
b. determine the correct classification for the dealing(s) to be conducted;
c. complete an appropriate application form and submit to the LTIBC for assessment per the process outlined on the EIB website; and
d. if required, consult with the LTIBC to ensure appropriate classification and scope of their application.

(19) Licenced Dealings (i.e. DNIR or DIR) must be discussed with the LTIBC well in advance of an application. It is likely that consultation with the Office of the Gene Technology Regulator (OGTR) will be required prior to submission to the LTIBC for assessment and submission of a licence application to the Regulator.

(20) Application assessments will be undertaken by LTIBC members with appropriate expertise to ensure that dealings are appropriately classified and that applicable controls will be in place to ensure safety of people, animals and the environment.

(21) Approvals are for a maximum period of 5 years as set out in the Gene Technology Regulations 2001. An approval will be in the form of a Record of Assessment (RoA) that sets out the scope and boundaries of the program approval (e.g. what classes of GMO are approved, what classes of persons are covered and what certified containment facilities the dealings can be undertaken). As such, the LTIBC encourages researchers to consider the scope of their applications over this time period. The LTIBC can provide guidance to researchers on how to scope their applications and will endeavour to assess applications as broadly as possible.

(22) Approvals from another IBC may be accepted by the LTIBC. Requests for transfers and acceptance of other IBC approvals (i.e. RoAs) should be directed to the LTIBC via biosafety@latrobe.edu.au.

(23) Approvals for a third-party applicant may be considered on a case-by-case basis. The LTIBC can review and approve projects for a third-party where there is no overarching research agreement. Review and approval will be contingent on contractual agreements that outline the indemnification of IBC members, clearly defined roles and responsibilities, and governance oversight in accordance with the La Trobe Research Governance Framework and associated policies and procedures. Assessments will be provided on a fee-for-service basis.

(24) Variations cannot be made to RoA. Amendments can, however, be made to the list of approved persons and the current facilities list associated with an approval. This can be undertaken through a notification to the LTIBC via biosafety@latrobe.edu.au. Other changes in the scope of an approval should be checked with the LTIBC. For example, checking if a proposed dealing is within the scope of the RoA. If the work is outside the scope of current approvals, then a new application is required for LTIBC assessment.

(25) Training is an integral part of compliance. The Senior Manager, Ethics Integrity and Biosafety oversees the development, delivery and review of training designed for personnel who work with GMOs and/or require access to OGTR certified Physical Containment Facilities at La Trobe. All personnel listed on GMO dealings must complete this training. Personnel who do not conduct research involving gene technology, but work within or require access to OGTR certified Physical Containment Facilities must also complete the training. If requested, the LTIBC will also assist facility managers and supervisors in the development and delivery of specific training packages (e.g. NLRD or licence specific training, contractor awareness training etc.).

(26) Licence and certified Physical Containment Facility training may also be required and provided by the LTIBC and/or the facility operator.

(27) Annual Reporting of all new GMO dealings to the OGTR is a requirement under 'the Act'. Institutional Reporting is undertaken on behalf of researchers by the LTIBC Executive Officer.

(28) Internal reporting consists of annual monitoring of approved dealings and regular reports to the Research and Graduate Studies Committee (RGSC) via the LTIBC. The annual check asks researchers to describe/list what they are adding to the project in the coming year and the LTIBC evaluates and confirms whether the additions are within the scope of the existing RoA or whether a new application is required.

(29) Project completion reports are required to be submitted to the LTIBC to ensure that all GMOs associated with a program are either transferred to another approval or destroyed in accordance with the OGTR Guidelines for Transport Storage and Disposal.

(30) Legislative requirements and responsibilities of persons working with GMOs are provided through training and the application process. Further support is available from within Schools and from the LTIBC, as required.

Part C - General Biosafety Support and Advice

(31) Personnel may require approvals for the biological agents they intend to work with. If required, personnel should consult with the LTIBC to ensure the necessary approval(s) are in place as well as the appropriate biosafety support for the project.

(32) The types of activities that may require approvals that the LTIBC can assist with include, but are not limited to:

a. dealings with genetically modified organisms (gene technology);
b. projects using new breeding technologies (gene editing);
c. import and export of biological material (biosecurity and quarantine);
d. biosafety risk assessments–for laboratory and field-based activities;
e. dual use organisms as listed by the federal Health Minister (security sensitive biological agents);
f. Material Transfer Agreements (MTAs)for receiving or sending biological materials that may have commercial potential;
g. facility upgrades, new builds and minor works, particularly those that require physical or quarantine containment certification; and
h. risk assessments for biological agents, processes and procedures.

Part D - Assistance and Support for Biosecurity Related Activities

(33) All processes and activities involving quarantine are regulated in Australia through the Biosecurity Act 2015. In accordance with this legislation, governance and oversight for biosecurity matters at La Trobe is provided by the LTIBC and supported by the EIB team.

(34) Biosecurity related import permits and Approved Arrangement sites are held directly within Schools. At La Trobe, the application for new Approved Arrangements, Biosecurity Containment Facilities and subsequent monitoring inspections are managed by EIB team. All questions regarding importation permits and Approved Arrangement facilities should be directed to the LTIBC at biosafety@latrobe.edu.au.

Part E - Certified Physical/biosecurity Containment Facilities

(35) All dealings with GMOs and some quarantine items are required to be undertaken within certified

physical/biosecurity containment facilities, typically, for GMOs, Physical Containment Level 1 (PC1) or Physical Containment Level 2 (PC2) and under the Biosecurity Act 2015, Biosecurity Containment Level 1 (BC1) or Biosecurity Containment Level 2 (BC2). These are facilities that have been assessed and certified to meet the most current OGTR Guidelines for the Certification of Physical Containment Facilities (level and type) or the Department of Agriculture, Fisheries and Forestry (DAFF) Biosecurity Containment requirements and incorporating best practice requirements outlined in the Australian/New Zealand Standard AS/NZS 2243: 3 (Safety in laboratories: Microbiological safety and containment). DAFF will issue a Notice of Approval and the OGTR provide a certification instrument that outlines the details of the certified/approved facility, the period for which the facility is certified and any applicable conditions or variations.

(36) Access to certified Physical/Biosecurity containment facilities is restricted to authorised persons only. The facility manager will provide authorisation and access after persons have completed the necessary training and inductions. Unauthorised persons may only enter certified Physical/Biosecurity containment facilities with the permission of the facility manager and unauthorised persons must not conduct any dealings with GMOs or biosecurity-controlled items. Unauthorised persons may include, for example, contractors, maintenance staff and visitors. It is a requirement of certification that Monitoring and Compliance officers from the OGTR or Biosecurity Auditors from DAFF be allowed unrestricted access.

(37) Requests for certification or accreditation of facilities should be directed to the LTIBC via biosafety@latrobe.edu.au. The EIB team and facility manager are responsible for collating the additional paperwork required for the certification application. Applications must be authorised by the SDVCRIE prior to submission to the OGTR or DAFF. The EIB team must liaise with the OGTR or DAFF to ensure that any outstanding certification requirements are resolved. Once certification is granted by the OGTR or DAFF, the EIB team is responsible for retaining a copy for the University records and forwarding the certification and signage to the facility manager.

(38) In accordance with 'the Act', PC2 facilities and Approved Arrangements must be inspected at least every 12 months by the LTIBC or their nominee. PC1 facilities must be inspected every 2 years. DAFF will undertake routine audits of Biosecurity Containment Facilities.

(39) Facility inspections assess whether the existing certified Physical Containment Facility continues to meet the conditions and requirements of certification. This includes ensuring that the facility provides effective containment and that persons working in the facility are adhering to the certification behavioural requirements. It is also an opportunity to discuss any issues that users may have with working in the facility. The LTIBC will undertake facility inspections, including a review of GMO registries and biosecurity-controlled material held within a facility.

(40) Persons undertaking an inspection will usually be accompanied by the facility manager or a suitable nominee and it is often beneficial to have a researcher that has approved dealings within the facility also present.

(41) Upon completion of the inspection, the EIB team must notify the facility manager of the outcomes and details of any action items that require attention, and a proposed timeframe for completion of action items. The facility manager must provide written confirmation that all action items have been resolved. Failure to address action items and provide written confirmation may result in the suspension or surrender of the certification status. Where required, the EIB team will work with the facility manager to ensure ongoing compliance with the certification instrument. The University must maintain inspection reports for a minimum of 3 years and provide these to the Regulator upon request.

(42) Approved Arrangements expire after 10 years, unless otherwise specified in the Notice of Assessment. The certification instrument of a facility lasts for 5 years and can be varied, suspended and renewed. Any proposed changes to the certification status must be discussed with the LTIBC, who will liaise with the OGTR and/or DAFF to amend the instrument.

(43) Any minor or emergency works required to be undertaken within the facility should be discussed with the LTIBC

before commencement. The LTIBC can provide advice on ensuring containment and adherence to the certification instrument. For some works, the certification may need to be suspended prior to works being undertaken and then re-certified. This administrative process can take several months, so it is advisable to seek advice from the LTIBC well in advance of any works.

(44) Any real or suspected release of genetically modified materials or quarantine items outside of a certified Physical/Biosecurity Containment Facility not approved by the Gene Technology Regulator or DAFF, including spills, must be reported as soon as reasonably possible by the responsible personnel to the EIB team, who must report any unintentional release of a GMO to the Gene Technology Regulator or a quarantine item to DAFF as soon as reasonably possible.

Part F - Confidential Commercial Information and Conflicts of Interest

(45) The LTIBC regards any and all information provided to them by stakeholders as confidential commercial information (CCI). Stakeholders are encouraged to identify specific elements in correspondence and applications that they regard as CCI. Where applicable, advice and guidance should be sought from consultation with the Office of the Pro Vice-Chancellor (Industry Engagement).

(46) The LTIBC will deal with situations in which a conflict of interest arises, including any situation where a member of LTIBC has an interest that may be seen to influence the objectivity of a decision. LTIBC members must declare any such conflict of interest whether direct or indirect, financial or otherwise, actual, potential or perceived. The LTIBC will deal with conflicts of interests by:

a. Requiring members to disclose the nature of their interest and conflict as soon as practicable after they become aware of anything that may be reasonably considered to be a conflict of interest.
b. Making it a requirement to declare conflicts of interest at the start of each LTIBC meeting and to document the declarations and resolutions in the minutes of the quorate meeting.
c. Requiring a member whose objectivity may be influenced by an interest (including consideration of a proposal submitted by that member) to leave the meeting at an appropriate time (certainly during the decision-making process).
d. Considering and responding to any concern raised by an investigator or other party that a LTIBC member has an interest that may have influenced the objectivity of a LTIBC decision. In this case, the Chairperson must advise the complainant, in writing, of the LTIBC response. If the complainant is not satisfied with the LTIBC response, a grievance may be lodged with the Research and Graduate Studies Committee or the University Ombudsman.
e. Allocating applications for review to members not from the same research or collaborative group as the applicant.
f. Providing advice on matters of conflict of interest, without breaching confidentiality.

Part G - Monitoring of LTIBC Approvals

(47) The frequency of monitoring or will depend on the degree of risk that arises from the research and should be proportionate to that risk.

(48) The purpose of monitoring is to:

a. ensure that the laboratory dealings are within the scope of LTIBC approvals and that the class(es) of people involved in the work are appropriately trained, class(es) of facilities are appropriate to the dealings and that the Guidelines for Transport, Storage and Disposal are being followed;
b. educate and assist researchers to understand the scope of their approvals and when a new approval is

required;

c. ensure that appropriate training is given and that the risk assessment is communicated from the Principal Investigator to the entire research team and to key stakeholders;
d. evaluate how risk assessments are communicated and how risks controls are implemented; and
e. ensure there is opportunity for feedback undertaken for continuous improvement.

(49) Monitoring will be arranged in collaboration with facility managers and researchers.

(50) The following will be included in the monitoring checklist:

a. Scope of approvals
b. Compliance with LTIBC approval including review of:
    i. Class(es) and type(s) of GMOs and GMO registries
    ii. Class(es) or personnel and training: All researchers, whether staff or students involved in the receipt, storage, handling, transport, use and disposal of GMOs must receive appropriate induction, training and management supervision, and this training must be documented.
    iii. Class(es) of facilities
    iv. Risk Assessment and Risk Management
c. Compliance with the OGTR Guidelines for Transport, Storage and Disposal of GMOs. This includes transport between approved facilities and institutions and the import and export of GMOs.

(51) Monitoring performance (including auditing, inspection and any corrective action) will be documented and communicated to the researchers.

(52) Results of performance monitoring including close-out of any corrective actions will be reported to the LTIBC.

(53) Any concerns of research integrity and any potential breaches will be reported to the Senior Manager, Ethics Integrity and Biosafety.

Part H - Monitoring of Certified Physical Containment Facilities

(54) The LTIBC will conduct annual inspections of certified Physical Containment Facilities as per ‘the Act’ and associated Regulations.

(55) LTIBC facility inspections will assess whether the existing certified Physical Containment Facility continues to meet the conditions and requirements of certification. This includes ensuring that the facility provides effective containment and that persons working in the facility are adhering to the certification behavioural requirements.

(56) Persons undertaking an inspection will usually be accompanied by the facility manager or a suitable nominee.

(57) Upon completion of the inspection, the EIB team must notify the facility manager of the outcomes and details of any action items that require attention, and a proposed timeframe for completion of action items.

(58) The facility manager must provide written confirmation that all action items have been resolved within the approve time frame. Failure to address action items and provide written confirmation may result in the suspension or surrender of the certification status.

(59) Where required, the EIB team will work with the facility manager to ensure ongoing compliance with the certification instrument. The University must maintain inspection reports for a minimum of 3 years and provide these to the Regulator upon request.

Section 7 - Definitions

(60) For the purposes of this procedure:

a. Approved Arrangement: Voluntary arrangement entered into with DAFF that allows the University to manage biosecurity risks in accordance with departmental requirements while using its own sites, facilities, equipment, and people.
b. Biosafety: Containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release.
c. Biological agents: Bacteria, fungi (yeasts and moulds), protozoans and other parasites, viruses, viroids, prions.
d. Biosecurity: Institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.
e. Biological risk management and containment: means The application of good practice controls to manage the containment of genetically modified organisms (GMOs).
f. Biological research and teaching activities: Research and teaching activities that involve working with biological agents including 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.
g. Compliance: The outcome of an organisation meeting its obligations (as defined in the University's Compliance Management Policy), and the actions of all staff, according to their role within the University, conforming to all applicable laws and regulations.
h. Containment: The combination of buildings, engineering function, equipment, and worker practices used to handle microorganisms and prions safely.
i. 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.

a. Facility operator: facility owner or lessee.
b. Gene Technology: any technique for the modification of genes or other genetic material, excluding sexual reproduction; homologous recombination; or any other item mentioned in Schedule 1A of the Regulations.
c. Genetically Modified Organism (GMO): an organism that has been modified by gene technology, or an organism that has inherited particular traits from an organism (initial organism) that are traits stemming from the initial organism being modified by gene technology.
d. LTIBC: La Trobe Institutional Biosafety Committee.
e. OGTR: Office of the Gene Technology Regulator.
f. Physical Containment Facility (PC1-PC4): a specific type of facility such as a building, laboratory, glasshouse,

insectary or animal house, certified by the OGTR to a specified containment level for the purpose of preventing the release of GMOs into the environment, to protect persons outside the facility from exposure to GMOs and protects the safety of people working with GMOs inside the facility.

g. Principal Investigator: refers to the researcher primarily responsible for the conduct of research.
h. Risk: The likelihood a hazard will cause harm (injury or ill health) and the degree of harm (consequence).
i. Risk assessment: process of evaluating the risk(s) arising from the hazard(s), taking into account the adequacy of any existing controls, deciding whether or not the risk(s) is acceptable, and taking further action as required.

Section 8 - Authority and Associated Information

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

(62) Refer to the Associated Information page, where you will find a list of the most relevant Australian law relating to this topic. Note that the list of legislation is not comprehensive.

(63) Associated information includes:

a. Ethics, Integrity and Biosafety website

Status and Details

Status	Current
Effective Date	26th July 2023
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Expiry Date	Not Applicable
Responsible Manager - Policy	Mark Li Senior Manager, Ethics Integrity and Biosafety
Enquiries Contact	Ethics, Integrity and Biosafety

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