Research Biosafety and Biosecurity Procedure

Section 1 - Background and Purpose

(1) La Trobe University is committed to the health and safety of its' staff and students, the community and the environment. All personnel who intend to conduct research or teaching projects 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;
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 persons 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;
c. undertake activities within a best practice and compliant framework, and
d. are willing to comply.

(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 meet obligations–persons understand and can deliver innovative and efficient solutions that are both practical and compliant;
e. monitoring of compliance–through internal and external audits that are both vertical and horizontal, providing

f. pathways for continuous improvement and compliance;
g. procedural fairness and continuous improvement–encouraging and fostering a good compliance culture within La Trobe University;
h. processes and procedures for dealing with non-compliance.

Section 2 - Scope

(7) This Procedure applies to:

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

Section 3 - Policy Statement

(8) Refer to the Research Biosafety and Biosecurity Policy.

Section 4 - Procedures

Part A - Governance and Oversight

(9) The Deputy Vice-Chancellor (Research and Industry Engagement) (DVC(R&IE)) 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 delegate) through the Research Office is responsible for the promulgation and 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 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; and
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 these comply with the certification requirements.
e. Conducting internal audits or "health checks" of approved projects to ensure compliance with the Biosafety and Biosecurity Policy and the Biosafety and Biosecurity Procedure.
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 biologicals 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 and or internal audit processes by the La Trobe Institutional Biosafety Committee.
f. raising any issues of non-conformity, non-compliance or breach with the La Trobe Institutional Biosafety Committee.

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

a. ensuring that all work involving GMOs has prior approval by the La Trobe Institutional Biosafety Committee 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 genetically modified organisms (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 La Trobe Institutional Biosafety Committee any intended use of genetically modified organisms (GMOs).
d. contributing to faculty 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.
g. reporting any incidents to the relevant research supervisor/s and/or manager/s.

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 La Trobe Institutional Biosafety Committee. 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 Biosafety, biosecurity and gene technology research website.

(18) Researchers wishing to conduct dealings should:

a. refer to the biosafety, biosecurity and gene technology research 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 website.
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 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 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 mutually recognised by the LTIBC. Requests for transfers and recognition of other IBC approvals (i.e. RoAs) should be directed to the LTIBC Executive Officer 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 fee-for-service basis.

(24) Variations cannot be made to Records of Assessment. Amendments can, however, be made to the list of approved persons and the current facility list associated with an approval. This can be undertaken through a notification to the LTIBC Executive Officer 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 Record of Assessment. If the work is outside the scope of current approvals, then a new application would be required for LTIBC assessment.

(25) Training is an integral part of compliance. The Senior Manager, Ethics Integrity and Biosafety coordinates 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 an annual health check of approved dealings and regular reports to the RGSC via the LTIBC Executive Officer. The annual health check asks researchers to describe/list what they are adding to the

project in the coming year and the LTIBC assesses and confirms whether the additions are within the scope of the existing RoA or trigger a new application.

(29) Project completion reports are required to be submitted to the LTIBC Executive Officer 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 that deal 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 want 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. Gene Technology–dealings with genetically modified organisms;
b. Gene Editing–projects using new breeding technologies;
c. Biosecurity and Quarantine–import and export of biological material;
d. Biosafety Risk Assessments–for laboratory and field-based activities;
e. Security Sensitive Biological Agents–Dual use organisms as listed by the federal Health Minister;
f. Material Transfer Agreements–ensuring appropriate approvals are in place 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;
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 Research Office.

(34) Quarantine related import permits and Approved Arrangement sites (AA 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 Ethics, Integrity and Biosafety. All questions regarding importation permits and quarantine approved premises should be directed to the LTIBC Executive Officer 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 (PC1) or Biosecurity Containment Level 2 (PC2). 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, Water and the Environment (DAWE) 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). The OGTR and DAWE provide a Certification Instrument that outlines the details of the certified/approved facility and any special conditions or variations that maybe applicable.

(36) Access to certified physical/biosecurity containment facilities is restricted to authorised persons only. The Facility Manager/Supervisor will provide authorisation and access only once 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/Supervisor and unauthorised persons must not conduct any dealings with GMOs or quarantine 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 DAWE be allowed unrestricted access.

(37) Requests for certification of facilities should be directed to the LTIBC Executive Officer via biosafety@latrobe.edu.au. The Executive Officer and Facility Manager/Supervisor are responsible for collating the additional paperwork required for the certification application. Applications must be authorised by the DVC(RIE) prior to submission to the OGTR or DAWE. The Executive Officer must liaise with the OGTR or DAWE to ensure that any outstanding certification requirements are resolved. Once certification is granted by the OGTR or DAWE, the Executive Officer is responsible for retaining a copy for the University records and forwarding the certification and signage to the Facility Manager/Supervisor.

(38) In accordance with 'the Act', PC2 facilities must be inspected at least every 12 months by the LTIBC or appropriately trained person(s). PC1 facilities must be inspected every 2 years. DAWE 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 held within a facility.

(40) Persons undertaking an inspection will usually be accompanied by the Facility Manager/Supervisor 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 LTIBC Executive Officer must notify the Facility Manager/Supervisor of the outcomes and details of any action items that require attention, and a proposed timeframe for completion of action items. The Facility Manager/Supervisor 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 LTIBC Executive Officer will work with the Facility Manager/Supervisor 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) 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 DAWE 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 DAWE, including spills, must be reported as soon as reasonably possible by the responsible personnel to the LTIBC Executive Officer. The LTIBC Executive Officer must report any unintentional release of a GMO to the Gene Technology Regulator or a quarantine item to DAWE 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, perceived or real. The LTIBC will deal with real or potential 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 “health checks” will depend on the degree of risk that arises from the research and should be proportionate to that risk.

(48) The purpose of “health checks” are 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 project supervisor to the entire research team and to key stakeholders.
d. monitor how risk assessments are communicated and how risks controls are implemented.
e. ensure there is opportunity for feedback undertaken for continuous improvement.

(49) Health checks 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 La Trobe Institutional Biosafety Committee

(53) Any concerns of research integrity and any potential breaches will be reported to the 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/Supervisor or a suitable nominee.

(57) Upon completion of the inspection, the LTIBC Executive Officer must notify the Facility Manager/Supervisor 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/Supervisor 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.

(59) Where required, the LTIBC Executive Officer will work with the Facility Manager/Supervisor 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 5 - Definitions

(60) For the purposes of this procedure:

a. Biosafety: Containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release.
b. Biological agents: Bacteria, fungi (yeasts and moulds), protozoans and other parasites, viruses, viroids, prions.

c. Biosecurity: Institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.
d. Biological risk management and containment: means The application of good practice controls to manage the containment of genetically modified organisms (GMOs).
e. 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.
f. 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.
g. Containment: The combination of buildings, engineering function, equipment, and worker practices used to handle microorganisms and prions safely.
h. Dealing: to conduct experiments with a GMO; make, develop, produce or manufacture a GMO; breed, propagate, grow, raise or culture a GMO; import, transport or dispose of a GMO; use a GMO in the course of manufacturing something that is not a GMO; and the possession, supply or use of a GMO for the purposes of, or in the course of any of the dealings already mentioned.
i. 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.
j. 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.
k. Dealing: to conduct experiments with a GMO; make, develop, produce or manufacture a GMO; breed, propagate, grow, raise or culture a GMO; import, transport or dispose of a GMO; use a GMO in the course of manufacturing something that is not a GMO; and the possession, supply or use of a GMO for the purposes of, or in the course of any of the dealings already mentioned.
l. LTIBC: La Trobe Institutional Biosafety Committee.
m. OGTR: Office of the Gene Technology Regulator.
n. 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.
o. Risk: The likelihood a hazard will cause harm (injury or ill health) and the degree of harm (consequence).
p. 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.

Status and Details

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Responsible Policy Officer	Alistair Duncan Executive Director, Research Office
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