Genetically Modified Organisms Procedure

Section 1 - Background and Purpose

(1) Hazardous organisms including those created with new technologies bring about fresh and untested challenges regarding their benefits and the potential hazards they may introduce. The manipulation of genetic material, in particular work with gene technology, attracts intense scrutiny by the wider community. There is great expectation by the public that risks associated with this type of research are identified and managed accordingly to protect the health and safety of people and the environment.

(2) La Trobe University is committed to identifying and managing any risks associated with the use of gene technologies in order to protect the health and safety of La Trobe personnel, students, the broader community and environment. The University aims to ensure La Trobe University personnel, students and visitors at all La Trobe campuses adhere to the current legislative frameworks applying to gene technologies.

(3) In accordance with Gene Technology Act 2000, a genetically modified organism (GMO) is defined as:

a. an organism that has been modified by gene technology; or
b. 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
c. anything declared by the regulations to be genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms but does not include:
    i. a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene technology; or
    ii. an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

(4) Modification of nucleic acid to create a GMO is commonly referred to as ‘gene technology’ and involves the genetic modification of organisms by incorporation or deletion of one or more genes to introduce or alter a specific characteristic or characteristics. Recent advances in gene technology research have seen the emergence of new technologies that enable the introduction of very precise changes to genetic material, allowing the transfer of properties of a single gene from one organism to another to form GMOs.

Section 2 - Scope

(5) Refer to the Research Integrity Policy.

Section 3 - Policy Statement

(6) Refer to the Research Integrity Policy.

Part A - Regulatory Environment

(7) 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 (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.

(8) 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.

(9) The LTIBC is a sub-committee of the Research and Graduate Studies Committee (RGSC) which is chaired by the DVC(R).

Part B - Relevant Legislation and Guidelines

(10) The national regulatory system for gene technology is set out in the Gene Technology Act 2000 (the Act) and Gene Technology Regulations 2001 (the Regulations), in conjunction with corresponding State and Territory legislation, underpinning the scheme for the regulation of live and viable GMOs in Australia.

(11) In the Act, dealings with GMOs are categorised according to their risk potential and the necessary mandatory precautions for each type of dealing are identified. The OGTR provides technical and regulatory support and guidance to institutions and organisations undertaking gene technology work and monitors and enforces compliance with the Act.

(12) Research may also be subject to conditions under the Biosecurity Act 2015, the National Health Security Act 2007 and the Defence Trade Controls Act 2012 and the Customs Act 1901.

(13) In addition to the requirements of the Act, research involving genetically modified animals must be conducted in accordance to the Guidelines for the Generation, Breeding, Care and Use of Genetically Modified and Cloned Animals for Scientific Purposes (2007), State and Federal animal welfare legislation and obtain ethical clearance for the use of animals.

Part C - Role of the La Trobe Institutional Biosafety Committee

(14) The La Trobe Institutional Biosafety Committee (LTIBC) provides researchers who are seeking assistance, with professional and unfettered advice on the risks associated with gene technologies and best practice. As determined by the Academic Board, the LTIBC is an authorised body recognised by the Gene Technology Regulator, with Terms of Reference aligned with the obligations of the University under the Act, Regulations and corresponding State legislation.

(15) At La Trobe all activities involving GMOs or utilising gene technologies must be assessed and approved by the LTIBC and may require AEC and/or UHEC approval. The Committee must apply a set of principles as outlined in the Act and Regulations that govern the classification of GMO dealings, the containment of those dealings and the conduct of people whose work involves recombinant nucleic acid or gene technology. Activities involving GMOs or gene technologies must not commence prior to the receipt of written approval by the LTIBC. The Committee assesses activities to ensure that any real or potential hazards concerning dealings with GMOs are identified and managed appropriately, research environments conform to certification rules or containment principles and informs the OGTR and RGSC of dealings with GMOs at La Trobe.

(16) Policy support and secretariat to the LTIBC is provided by the Research Office.

Part D - Submission of Dealings to LTIBC

(17) 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 (DNIR and DIR).

(18) Detailed descriptions of each class and corresponding application forms are available on the Biosafety, biosecurity and gene technology research website.

(19) 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 to be conducted.
c. Download the appropriate application form, complete and submit the application electronically to biosafety@latrobe.edu.au from the project Chief Investigator's La Trobe email account. This method enables legal receipt of applications without a signature.

Part E - Assessment Process of Dealings by LTIBC

(20) Applications are assessed in order of receipt. The LTIBC Executive Officer firstly vets new applications for completeness and notifies researchers of any additional requirements. Applications will be allocated a La Trobe reference number and provided to LTIBC members for review and comment.

(21) Applications are assessed according to the Act and Regulations. In evaluating an application for an Exempt dealing, the Committee must establish that all Exempt dealings are correctly classified, with respect to Schedule 2 of the Gene Technology Regulations 2001 (and any amendments). In evaluating an application for an NLRD, the Committee must establish:

a. That the NLRD has been correctly classified with respect to Schedule 3 of the Gene Technology Regulations 2001.
b. Confirm that the information in relation to an NLRD is complete, including information in relation to the transport, storage and disposal of genetically modified materials.
c. Evaluate the proposal for an NLRD and that any risks posed by the dealing are identified and appropriate management strategies are in place.
d. Confirm that personnel are adequately trained and experienced, or a combination of both, to undertake the dealing.
e. Confirm that the facilities are of an appropriate type and level of containment for the dealing classification.
f. Complete a Record of Assessment and provide a signed copy to the project Chief Investigator.

(22) In evaluating an application for a licensed dealing, the Committee must:

a. Review and support the application and any supporting information provided in the application as per the requirements of the Gene Technology Regulator.
b. Following review and approval, forward the application and supporting information to the Gene Technology Regulator who will undertake an assessment and undertake public consultation through the publication of a Risk Assessment Risk Management Plan.

(23) Applicants will be notified of the review outcome approximately 6 weeks (at least 30 working days) from submission. Notification times vary based on the volume of applications under review and the level of detail or clarity

of information provided in an application. Once the review has been completed, the Executive Officer must follow up on additional or outstanding information cited by the reviewers, and forward the completed paperwork to the reviewers and Chair for consideration.

(24) If an application is rejected, the Executive Officer must notify the researcher in writing of the reasons why the application was rejected. If an application is approved, approval is granted on the condition that all research will be conducted in accordance with the Gene Technology Act 2000, Australian/New Zealand Standard AS/NZS 2243: 3 (Safety in laboratories: Microbiological safety and containment) and all La Trobe University conditions outlined in the LTIBC approval letter.

(25) Licensed dealings must be submitted to the LTIBC for review. The LTIBC Executive Officer will forward license dealings approved and supported by the LTIBC to the OGTR for approval after hard copy signatures have been obtained from the project supervisor, LTIBC Chair and DVC(R). Licensed dealings approved by the LTIBC must not commence prior to written approval by the Gene Technology Regulator.

(26) Depending on the type of dealing and scope of the request, applications to vary an approved project may be considered throughout the year. As a condition of approval, Chief Investigators must request approval from the Committee for any minor variations to an approved project. Requests that alter the original scope of the approved dealing require the submission of a new application. Minor variation requests will be reviewed as delegated by the Committee to the Executive Officer and LTIBC Chair and may be put to committee members for review.

Part F - Research Assessed by an External IBC

(27) The LTIBC currently assess dealings conducted by an external Chief Investigator under an expedited review procedure on a case by case basis, provided the dealing has been approved by an accredited organisation's Institutional Biosafety Committee (IBC). External Chief Investigators requesting use of La Trobe University facilities to conduct dealing(s) must provide a copy of the project's IBC assessment, OGTR licence and conditions if applicable, and a summary of the gene technology research to occur at La Trobe University.

(28) The LTIBC reserves the right to place conditions on involvement or refuse involvement should approved proposals be assessed to potentially expose the University to undue risk. Reporting and administering requirements remain the responsibility of the IBC that assessed the dealing. Copies of reports and approved variations to dealings must be provided to the LTIBC while the dealing is conducted in La Trobe University facilities.

(29) Centre for AgriBioscience and La Trobe University Collaborations: Where the Chief Investigator is a La Trobe University staff member and the dealing is conducted in La Trobe University facilities, primary approval must be obtained from LTIBC. Where the Chief Investigator is a La Trobe University staff member and the dealing is conducted in Department of Economic Development, Jobs, Transport and Resources (DEDJTR)/ AgriBioscience facilities, primary approval must be obtained from AgriBioscience IBC and notification provided to the LTIBC for annual reporting purposes

(30) Higher risk dealings (DIRs and DNIRs) conducted by La Trobe University staff in AgriBioscience certified facilities must firstly receive approval from AgriBioscience IBC then receive secondary approval from LTIBC for the dealing to be forwarded to the OGTR for approval.

(31) Where the Chief Investigator is a La Trobe University staff member and the dealing is conducted in both La Trobe University and AgriBioscience facilities, project proposals must be submitted to both the LTIBC and AgriBioscience IBC. Where the Chief Investigator is a La Trobe University and DEDJTR joint appointee, primary approval must be obtained from AgriBiosciences IBC and notification provided to the LTIBC for annual reporting purposes.

Part G - Reporting Requirements

(32) Annual Progress Reports: Chief Investigators of licensed dealings (DNIRs or DIRs) or Notifiable Low Risk Dealings (NLRDs) must submit an Annual Progress Report to the LTIBC as a condition of project approval. Chief Investigators who fail to submit an annual progress report may have their ethical clearance revoked. LTIBC reviews all progress reports during the February meeting and reports the submission status and issues raised by researchers to the RGSC in the LTIBC Annual Report.

(33) Final Reports: All Chief Investigators must submit a Final Report within three months of the expiry date or conclusion of their project as a condition of project approval. Final reports are reviewed by the LTIBC and kept by the University as an official record from the Chief Investigator regarding the outcome of all GMOs used or produced during the approval period.

(34) Annual Progress and Final Report forms are available on the Biosafety, biosecurity and gene technology research.

Part H - Facilities

(35) All facilities seeking certification must meet the most current OGTR Guidelines for the Certification of Physical Containment Facilities (level and type) incorporating best practice requirements outlined in the Australian/New Zealand Standard AS/NZS 2243: 3 (Safety in laboratories: Microbiological safety and containment). LTIBC members or its representatives conduct inspections and must complete the appropriate application checklist for the facility type and level. Inspectors must be accompanied by the Facility Manager/Supervisor or a suitable nominee and it is advisable that a researcher intending to conduct dealing(s) within the facility be present to answer inspector questions. All items requiring rectification must be resolved for the application to proceed to the next stage.

(36) 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(R) prior to submission to the OGTR. The Executive Officer must liaise with the OGTR to ensure that any outstanding certification requirements are resolved. Once certification is granted by the OGTR, the Executive Officer is responsible for retaining a copy for the University records and forwarding the certification and signage to the Facility Manager/Supervisor.

(37) In accordance with OGTR guidelines, certified physical containment level 2 (PC2) facilities must be inspected at least every 12 months by the LTIBC or appropriately trained person(s). Certified PC1 facilities will be inspected every 2 years. Inspection personnel assess whether the existing certified facility continues to meet the conditions and requirements of certification. Inspectors must be accompanied by the Facility Manager/Supervisor or a suitable nominee and it is advisable that a researcher conducting dealings within the facility also be present to answer inspector questions. The Executive Officer must notify the Facility Manager/Supervisor of the inspection outcome and if items require rectification, detail what is required and the deadline 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 certification status and require all GMO dealings conducted in the facility cease until the facility is compliant and certification active. The Executive Officer will provide reminder notices to the Facility Manager/Supervisor, and when necessary Head of School and / or College Pro Vice-Chancellor prior to the LTIBC seeking a suspension or surrender of certification.

(38) The University must maintain inspection reports for a minimum of 3 years and provide these to the Regulator upon request.

(39) Access to OGTR certified facilities is restricted to authorised persons who have completed the training as approved by the LTIBC. One of the authorised trainings is the La Trobe University Working with Recombinant DNA training module. Unauthorised persons may only enter certified facilities with the permission of the Facility Manager/Supervisor and unauthorised persons must not conduct dealings in certified facilities. Unauthorised persons include contractors, maintenance staff and visitors.

Part I - Conflict of Interest

(40) 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 Chair person 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.
g. Maintaining an annual register of conflicts of interest.

Part J - Complaints and Adverse Events

(41) The University has established a complaints and grievances mechanism for La Trobe University personnel, students and persons external to the University to allow the voicing of concerns regarding the use of genetically modified organisms. Such concerns must be submitted in writing to the LTIBC Executive Officer or the Manager, Ethics and Integrity.

(42) Complaints or grievances by La Trobe University personnel about decisions reached by LTIBC must be submitted in writing to the DVC(R) or the University Ombudsman.

(43) Any real or suspected release of genetically modified materials or organisms outside of a certified facility not approved by the Gene Technology Regulator, 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 real or suspected unintentional release of GMOs to the Regulator as soon as reasonably possible.

Part K - Additional Operating Guidelines

(44) Other LTIBC operating guidelines such as rulings on record keeping by the LTIBC and investigators, investigator training and variations to existing projects must be endorsed by RGSC and, upon approval, be displayed in their most current form on the Biosafety, biosecurity and gene technology research website.

Section 4 - Definitions

(45) For the purpose of this Procedure:

a. 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.
b. 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.
c. 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.
d. 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.
    i. (Note: PC3 and PC4 are not applicable to La Trobe University)

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