Genetically Modified Organisms Procedure

Section 1 - Background and Purpose

(1) 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 recombinant DNA, 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) Recombinant DNA is formed by combining segments of DNA from different organisms. Work with recombinant DNA 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 recombinant DNA research have seen the emergence of new techniques 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 Genetically Modified Organisms (GMOs).

Section 2 - Scope

(4) Refer to the Research Integrity Policy.

Section 3 - Policy Statement

(5) Refer to the Research Integrity Policy.

Part A - Regulatory Environment

(6) Recombinant DNA research by La Trobe University full time, part time, casual or adjunct staff, students, and visitors at all campuses in Australia is regulated and monitored by the La Trobe University Genetic Manipulation Supervisory Committee (GMSC) through the Office of the Deputy Vice-Chancellor (Research) (DVC(R))). GMSC is a sub-committee of the Research and Graduate Studies Committee (RGSC) which is chaired by the DVC(R). The Office of the DVC(R) answers to and is monitored by the Office of the Gene Technology Regulator (OGTR).

Part B - Relevant Legislation and Guidelines

(7) The OGTR was established by the federal government to support the Gene Technology Regulator administer the national regulatory system for gene technology as set out in the Gene Technology Act 2000 (the Act). The Act and Gene Technology Regulations 2001 (the Regulations), in conjunction with corresponding State and Territory

legislation, underpin the national scheme for the regulation of live and viable GMOs in Australia.

(8) The objectives of the national laws are to protect the health and safety of individuals and the environment, by identifying risks posed by or as a result of gene technology, and by managing real and potential risks through the regulation or certain dealings with GMOs.

(9) 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 recombinant DNA work and monitors and enforces compliance with the Act.

(10) 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 Genetic Manipulation Supervisory Committee

(11) Seeking and obtaining assistance from an Institutional Biosafety Committee comprised of members able to provide professional and unfettered advice on the risks associated with gene technologies is fundamental for best practice. At La Trobe University this committee is called the Genetic Manipulation Supervisory Committee. As determined by the Academic Board, the GMSC 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.

(12) At La Trobe University all activities involving GMOs or gene technologies must be assessed and approved by the GMSC. GMSC must apply a set of principles as outlined in the Act and Regulations that govern the classification of dealings with GMOs, the containment of dealings with GMOs and the conduct of people whose work involves recombinant DNA or gene technology. Activities involving GMOs or gene technologies must not commence prior to the receipt of written approval by GMSC. The GMSC 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 and informs the OGTR and RGSC of dealings with GMOs at La Trobe University.

(13) Policy support and secretariat to the GMSC is provided by the Research Integrity Unit, Research Office.

Part D - Submission of Dealings to GMSC

(14) 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 University all classes of dealings must be reviewed by the GMSC prior to commencement. The three main classes of dealings are: Exempt Dealings, Notifiable Low Risk Dealings (NLRD) and Licensed Dealings.

(15) Detailed descriptions of each class and corresponding application forms are available on the La Trobe Recombinant DNA web site.

(16) Researchers wishing to conduct dealings should:

a. Refer to the La Trobe Recombinant DNA web site.
b. Determine the correct classification for the dealing to be conducted.
c. Download the appropriate application form, complete and submit the application electronically to gmsc@latrobe.edu.au from the project Chief Investigator’s La Trobe University email account. This method enables legal receipt of applications without a signature.

Part E - Assessment Process of Dealings by GMSC

(17) Applications are assessed in order of receipt. GMSC Secretariat firstly reviews applications for completeness; incomplete applications will be returned to the project Chief Investigator for attention and not registered as being received. Registered applications will be allocated a La Trobe reference number and provided to GMSC members for review and comment.

(18) 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.

(19) 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 for assessment.

(20) Applicants will be notified of the review outcome approximately 2-3 weeks 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 Secretariat must follow up on additional or outstanding information cited by the reviewers, and forward the completed paperwork to the reviewers and Chair for consideration.

(21) If an application is rejected, the Secretariat 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 GMSC approval letter.

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

(23) Depending on the type of dealing and scope of the request, applications to modify an approved project may be considered throughout the year. As a condition of approval, Chief Investigators must request approval from the Committee for any modifications to an approved project. Requests that alter the original scope of the approved dealing require the submission of a new application. Modification requests will be reviewed as per a new application.

Part F - Research Assessed by an External IBC

(24) GMSC currently assess dealings conducted by an external Chief Investigator under an expedited review procedure, 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 projects IBC assessment, OGTR licence and conditions if applicable, and a summary of the recombinant DNA research to occur at La Trobe University.

(25) GMSC 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 modifications to dealings must be provided to the GMSC while the dealing is conducted in La Trobe University facilities.

(26) 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 GMSC. Where the Chief Investigator is a La Trobe University staff member and the dealing is conducted in Department of Primary Industry (DPI) / AgriBioscience facilities, primary approval must be obtained from AgriBioscience IBC and notification provided to the GMSC for annual reporting purposes

(27) 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 GMSC for the dealing to be forwarded to the OGTR for approval.

(28) 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 GMSC and AgriBioscience IBC. Where the Chief Investigator is a La Trobe University and DPI joint appointee, primary approval must be obtained from AgriBiosciences IBC and notification provided to the GMSC for annual reporting purposes.

Part G - Reporting Requirements

(29) 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 GMSC as a condition of project approval. Chief Investigators who fail to submit an annual progress report may have their ethical clearance revoked. GMSC reviews all progress reports during the February meeting and reports the submission status and issues raised by researchers to the RGSC in the GMSC Annual Report.

(30) 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 GMSC 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.

(31) Annual Progress Reports and Final Reports are available on the La Trobe Recombinant DNA web site.

Part H - Facilities

(32) All facilities seeking certification must meet the most current OGTR Guidelines for the Certification of Physical Containment Facilities (level and type) as well as the Australian/New Zealand Standard AS/NZS 2243: 3 (Safety in Laboratories: Microbiological safety and containment). GMSC 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.

(33) The Secretariat 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 Secretariat must liaise with the OGTR to ensure that any outstanding certification requirements are resolved. Once certification is granted by the OGTR, the Secretariat is responsible for retaining a copy for the University records and forwarding the certification and signage to the facility Manager / Supervisor.

(34) OGTR certified physical containment level 2 (PC2) facilities must be inspected at least every 12 months by the GMSC or its representatives. Inspection teams 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 be present to answer inspector questions. The Secretariat 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 Secretariat will provide reminder notices to the facility Manager / Supervisor, and when necessary Head of School and / or College Pro Vice-Chancellor prior to the GMSC seeking a suspension or surrender of certification.

(35) The University must maintain inspection reports for a minimum of 5 years and provide these to the Regulator if requested. Access to OGTR certified facilities is restricted to authorised persons who have completed 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

(36) GMSC will deal with situations in which a conflict of interest arises, including any situation where a member of GMSC has an interest that may be seen to influence the objectivity of a decision. GMSC members must declare any such conflict of interest whether direct or indirect, financial or otherwise, perceived or real. The GMSC 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 GMSC 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 GMSC member has an interest that may have influenced the objectivity of a GMSC decision. In this case, the Chair person must advise the complainant, in writing, of the GMSC response. If the complainant is not satisfied with the GMSC 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

(37) 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 GMSC Secretariat or the Research Integrity Manager.

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

(39) 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 GMSC Secretariat. The GMSC Secretariat must report any real or suspected unintentional release of GMOs to the Regulator as soon as reasonably possible.

Part K - Additional Operating Guidelines

(40) Other GMSC operating guidelines such as rulings on record keeping by the GMSC and investigators, investigator training and modification to existing projects must be endorsed by RGSC and, upon approval, be displayed in their most current form on the GMSC web site.

Section 4 - Definitions

(41) 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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