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GENETICALLY MODIFIED ORGANISMS PROCEDURES

Parent Policy Title	Research Integrity Policy
Associated Documents	Research Misconduct Procedures Animal Ethics Procedures
Preamble	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.
General	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).
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1. Regulatory Environment	GMO research by La Trobe University staff and students is regulated and monitored by the La Trobe University Genetic Manipulations 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 Office of the Gene Technology Regulator (OGTR).
2. Relevant Legislation and Guidelines	OGTR was established by the federal government in conjunction with the *Gene Technology* Act 2000*,* or the *Act,* to protect individual health and safety and the environment against any potential risks posed by gene technology. OGTR provides regulatory support to institutions and organisations undertaking work with recombinant DNA and ensures compliance with the *Act* and its amendments. 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. Research on genetically modified animals should be conducted in accordance to the *Guidelines for the Generation, Breeding, Care and Use of Genetically Modified and Cloned Animals for Scientific Purposes (2007)*.
3. Role of the Genetic Manipulation Supervisory Committee	All research involving recombinant DNA and GMOs must be reviewed and approved by GMSC prior to commencement. GMSC must apply a set of principles, outlined in the *Act*, that govern the conduct of people whose work involves recombinant DNA or GMOs. GMSC ensures that • possible hazards concerning recombinant DNA and GMOs are identified and dealt with appropriately • research environments conform to certification rules • OGTR is informed about dealings with recombinant DNA and GMOs according to the *Act* Policy support and secretariat to GMSC is provided by the Research Ethics and Integrity Unit.
4. GMSC Terms of Reference	As determined by Academic Board, GMSC is an authorised body formed to: (i) Receive applications for projects involving recombinant DNA research, determine the information to be provided by applicants and seek advice from within the University or from other sources, of the possible hazards concerning recombinant DNA, involved in the proposed project (including possible hazards to the safety of the research personnel, to public health, and to animal or plant health and to the environment); (ii) Recommend approval of proposed projects, either absolutely or subject to conditions, provided that the DVC(R) shall be free to terminate any such approval at any time; (iii) Through the Chair of the Committee, advise the DVC(R) of decisions relating to the granting of licences to conduct, or participate in, research into recombinant DNA to members of staff and students;

	(iv) Through the Chair of the Committee, advise the DVC(R) of decisions relating to the safety precautions either generally or for particular projects, which must be observed by those involved in recombinant DNA research; (v) Assist the University to meet the requirements of the Gene Technology Act 2000 and the Gene Technology Regulations 2001 (and associated amendments); (vi) Provide advice to researchers to enable them to ensure that research carried out at the University complies with all legislation and with the guidelines set out by the Office of the Gene Technology Regulator of the Commonwealth Department of Health and Aged Care; (vii) Co-operate closely, for the purpose of evolving effective safety standards, with the OGTR with a view to making fully effective, the guidelines laid down from time to time by the Regulator; (viii) Provide advice to the University Insurance Officer and other University departments as required on matters relating to research involving genetic manipulation at the University; (ix) Report to the Regulator annually on membership of the IBC, current Exempt, Notifiable Low Risk Dealings, and Licensed Dealings being conducted, certified PC2 Facilities, any contraventions of the legislation, any other matters that the University deems it necessary to draw to the Regulator's attention; (x) Maintain a list of people working on genetic manipulation research in Physical Containment facilities; (xi) Through appropriately qualified members of the IBC, carry out annual inspections of all containment facilities against the Regulator's requirements for containment and inspect new PC2 facilities for which certification from the Regulator is sought; (xii) Promulgate information about appropriate supervisory measures, thereby ensuring that safety guidelines laid down for particular projects are meticulously adhered to in the day-to-day conduct of research; (xiii) Establish a register of recombinant DNA research projects and ensure that this register is kept up-to-date by notification and registration of all significant modifications, including particularly such modifications as might tend to make the project more hazardous; (xiv) Inform itself of all developments that have a bearing upon potential hazards associated with recombinant DNA research, particularly those which lead to better understanding of the nature of such hazards and to improvements in containment techniques.

5. GMSC Membership	The La Trobe University GMSC must have a membership with membership categories as follows: A. The Chair to be a senior member of staff appointed by RGSC. B. A microbiologist experienced in the handling of pathogenic micro-organisms, nominated on the advice of the Dean and Faculty Board of the Faculty of Science, Technology and Engineering. C. A biologist familiar with the technique and concepts of recombinant DNA research, nominated on the advice of the Dean and Faculty Board of the Faculty of Science, Technology and Engineering. D. An evolutionary ecologist/agronomist familiar with gene flow and population biology, nominated by the Dean and Faculty Board of the Faculty of Science, Technology and Engineering. E. An engineer with expertise in the testing of biological cabinets, air pressures and filters and related equipment, or whose background would enable him/her to be trained readily in points of concern. Nominated by the Manager, Buildings and Grounds. F. Biological Safety Officer, a biologist chosen from amongst the Committee members, experienced with problems of biohazard and safety to act as technical adviser to the Committee. Nominated by GMSC. G. One representative based at the Bendigo Campus, La Trobe University, to be nominated by the Dean and Faculty Board of the Faculty of Science, Technology and Engineering. H. Lay person, not associated with the University and not directly involved in gene technology, who is in a position to consider the wider community issues. Nominated by GMSC. I. Power to co-opt three additional members. The Committee should facilitate the gender equity in the Committee's composition and ensure that membership is reasonably representative of all Schools & relevant research areas in which recombinant DNA projects are in progress. J. Manager, Occupational Health and Safety, or nominee of Manager. Terms of office shall ordinarily be for two years, unless otherwise recommended by the relevant nominating body and approved by RGSC.
6. Conflict of Interest	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 by: (i) 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. (ii) 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. (iii) 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).

	(iv) Considering and responding to any concern raised by an investigator of 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. (v) Allocating applications for review to members not from the same Department as the applicant. (vi) Providing advice on matters of conflict of interest, without breaching confidentiality.
7. Multi-centre Research	GMSC currently processes multi-centre research applications (with external Chief Investigator) under an expedited review procedure, provided the application has been approved by another organisation's Institutional Biosafety Committee, may perform an expedited review to assess the risk to either La Trobe University staff or certified facilities. 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. Where the Chief Investigator is a La Trobe University staff member, primary approval must be obtained from GMSC.
8. Annual Reporting	GMSC must report regularly to RGSC, including minutes of GMSC meetings to be forwarded within two weeks after a meeting and annual reporting to be completed by 31 March covering the previous calendar year. The annual report must include: (i) numbers and types of projects assessed and approved or rejected; (ii) numbers of complaints received and how they were dealt with; (iii) procedural changes; (iv) administrative or other difficulties being experienced; and (v) any matters that may affect the University's ability to maintain accreditation with OGTR and / or compliance with Gene Technology Act & Gene Technology Regulations, and if necessary the provision of suitable recommendations. In addition, GMSC must complete an Annual Report to OGTR. The report must be authorised by RGSC and signed by the DVC(R).
9. Additional Operating Guidelines	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.

10. Complaints and Adverse Events	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 GSMC Secretariat. 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. Any release of genetically modified organisms not approved by OGTR must be reported promptly by the responsible personnel to the GMSC Secretariat.
11. Facilities	Facilities holding GMOs must be approved by GMSC and certified by OGTR prior to commencement of research. All certified facilities must be inspected at least annually by GMSC and problems addressed to the satisfaction of GMSC. The GMSC must notify OGTR of all compliance issues arising from inspections and provide details as to how they have or can be resolved.
Status	New format. The implementation of the latest version of this procedure supersedes all previous versions of this procedure.
Approval Body	Academic Board Meeting 433, 12 August 2009, item 433.3.2.
Initiating Body	Research and Graduate Studies Committee Meeting 120, 31 July 2009, item 120.5.1.7.
Definitions	**Genetic modification (of animals):** the use of any technique for the modification of genes or other genetic material but not including the use of natural processes such as sexual reproduction.
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