

Monash University Procedure

Procedure Title	Activities Involving Genetically Modified Organisms Australian Procedures
Parent Policy	Activities Involving Genetically Modified Organisms Policy
Date Effective	
Review Date	
Procedure Owner	
Category	Academic Quality and Standards
Version Number	1.0
Content Enquiries	Manager Research Ethics
Scope	All Monash University staff, students and visitors on Australian campuses
Purpose	Monash University will ensure maximum compliance with current legislative frameworks as they apply to all its activities and therefore has procedures for the review of such activities and the certification and ongoing inspection of facilities where those activities are conducted.
PROCEDURE STATEMENT	

1. Governance

All activities involving GMOs must be subjected to review and monitoring by the MUIBC. Such activities will not commence until MUIBC approval has been received, other than for work deemed exempt from the OGTR Regulations (see below).

Responsibility

All Monash University staff, students and visitors on Australian campuses

2. Submission of Dealings for review

- Dealings are subdivided into three main groups: Exempt Dealings, Notifiable Low Risk Dealings (NLRD) and Licensed Dealings. Full definitions can be found on the Monash University [Institutional Biosafety Committee website](#). Dealings are classified based on the potential risk to both humans and the environment, with Exempt Dealings having the lowest level of risk and Licensed Dealings posing the greatest level of risk.
- The review process is dependent on the level of risk:
 - Work meeting the criteria of an Exempt Dealing may commence immediately but notification of the dealing to MUIBC should be within six months from commencement.
 - Work meeting the criteria of an NLRD must not commence until written approval from MUIBC has been received.
 - Work meeting the criteria of a Licensed Dealing (DNIR, DIR) must not commence until written approval has been received from the OGTR.

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- Staff wishing to conduct dealings should first reference the [Monash Research Office website](#) to establish the type of dealing, then select, complete and submit electronically the appropriate form from the website to the MUIBC Secretary at any time.
- Applications will be reviewed by the MUIBC Secretary for completeness. Incomplete proposals will be returned to the staff member for their attention and will not be considered as having been submitted to the MUIBC Secretary.
- Complete applications will be uploaded onto the MUIBC workspace and comments sought from the MUIBC members.
- The MUIBC Chair will take into consideration the MUIBC members' comments when considering the application for approval.
- Staff will be notified of the review outcome approximately two weeks from submission. Any issues to be addressed are itemised in an email from the Committee Secretary. Proposals with no issues will receive an approval email and a copy of the application with the Chair's signature.
- Proposals that have issues to be addressed will be approved once the issues have been addressed to the satisfaction of MUIBC.
- Exempt and NLRDs will be considered approved once written notification from MUIBC has been received.
- Licensed Dealings approved by the MUIBC Chair will be forwarded to the OGTR for approval after a hard copy with original signatures has been forwarded to the MUIBC Secretary.

Responsibility

All Monash University staff, students and visitors on Australian campuses
MUIBC members, Chair and Secretary

3. Annual reporting

- MUIBC approves dealings without a defined end expiration date subject to the ongoing submission of satisfactory annual reports.
- MUIBC reports annually to the OGTR on current dealings conducted by the University on a July - June calendar year. An annual report is required each year for all dealings which have had approval for greater than 12 months. Such a report should be submitted by the first-named investigator no later than June 30 each year using the form available on the [Monash Research Office website](#).
- Failure to submit a timely annual report will result in MUIBC withdrawing its approval of the dealing.
- Any GMOs generated as part of an approved dealing for which approval has been withdrawn must be destroyed.
- A staff member wishing to continue work on a dealing for which approval has been withdrawn must provide a new submission to MUIBC for consideration.

Responsibility

All Monash University staff, students and visitors on Australian campuses
MUIBC members

4. Certification of facilities

- Facilities where NLRDs or DNIRs are to be conducted must be certified by the OGTR to the appropriate level of containment.

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- Facilities where PC1-NLRDs are to be conducted must be certified to a minimum level of PC1.
- Facilities where PC2-NLRDs are to be conducted must be certified to a minimum level of PC2.
- Facilities where DNIRs are to be conducted must meet the condition requirements as specified on the license. The OGTR will instruct the license holder as to the minimum containment level required for that dealing based on the level of risk and any additional conditions.
- Staff members should contact the MUIBC Secretary to arrange the inspection and application for certification of any Monash facility requiring OGTR certification.
- MUIBC or its representative shall conduct the inspection of any Monash facility requiring certification and will submit the necessary application to the OGTR.
- Work involving GMOs must not be conducted in the facility until such time that the certification sticker has been affixed to the entrance of the facility.

Responsibility

All Monash University staff, students and visitors on Australian campuses
MUIBC Chair and Deputy Chair
MUIBC Secretary

5. Access to OGTR-certified facilities

- Access to an OGTR-certified facility must be restricted to authorised persons.
- For the purpose of 5.1 an authorised person is a person who has:
 - been trained in the behavioural requirements listed in the OGTR Guidelines for Certification of Physical Containment Facilities and has not been excluded from the facility by the certification holder at the direction of the Regulator;
 - signed and dated records of attending such training either centrally through OHS or through the local Biosafety Officer.
- Access to an OGTR-certified facility by unauthorised persons may only occur if the person or class of person does not intend to undertake dealings and has the permission of the local Biosafety Officer, the facility manager and laboratory head.
- For the purpose of the above dot point an unauthorised person includes:
 - maintenance staff;
 - contractors;
 - visiting scientists/other visitors; and
 - students not designated to undertake activities in a specific certified facility.

Responsibility

All Monash University staff, students and visitors on Australian campuses
MUIBC Chair and Deputy Chair
MUIBC Secretary

6. Annual inspections of facilities

- A requirement of certification is that all Physical Containment (Level 2 and 3) facilities must be inspected at least every 12 months by a person that MUIBC considers to be suitably qualified to assess the facility's compliance with the conditions set out in the OGTR Guidelines for Certification of Physical Containment Facilities.

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- Records for PC2 facilities detailing the extent of compliance with the conditions of certification of annual inspections must be held by the Monash Research Office and the last inspection report made available for the regulator upon request.
- Records for PC3 facilities detailing the extent of compliance with the conditions of certification of annual inspections must be held by the Monash Research Office, and the inspection reports for the last five years must be made available for the regulator upon request

Responsibility

MUIBC Chair and Deputy Chair
MUIBC Secretary

7. Complaints

- All complaints about activities involving the use of gene technology, review of dealing applications, certification of facilities or administration of annual reporting requirements should be made to the Manager of the Research Ethics and Compliance Unit for resolution.
- Where the complaint cannot be handled by the Manager of the Research Ethics and Compliance Unit, the Chair or Deputy Chair of MUIBC will be consulted.
- The Chair or Deputy Chair of MUIBC will act on behalf of the Committee to fully investigate the complaint. This may involve seeking advice from the DVC(R)/(E), relevant Deans or Associate Deans or the University Solicitor. The investigation will at all times be conducted sensitively and within the requirements of relevant privacy legislation. If a breach of the OGTR legislation is identified, then MUIBC will inform the OGTR about the matter.
- The outcome of the investigation will then be communicated to the complainant and the staff member on behalf of the Committee. The head of the academic unit responsible for the conduct of the staff member will also be notified of the complaint and the resolution.
- Depending on the nature of the complaint and the resolution, it is possible that other processes may be instigated such as withdrawal of approval or initiation of staff misconduct or student misconduct procedures.
- If the matter cannot be resolved, a written request for resolution may be made to the DVC(R)/(E) by either the complainant or the Chair or Deputy Chair of MUIBC.
- The DVC(R)/(E) may then attempt to resolve the complaint through further negotiation or mediation, or may advise the complainant in writing that the complaint is considered to be lacking in substance, or frivolous and/or vexatious, and that no investigation is to be conducted.
- A complaint case would be considered closed upon receipt by the DVC(R)/(E) of a written withdrawal of the complaint by the complainant, or when the DVC(R)/(E) determines that there is nothing further that can be done in order to settle the complaint.
- Decisions of the DVC(R)/(E) may be appealed by the complainant in writing to the Vice-Chancellor. An appeal must be made within 28 days of receipt of the decision of the DVC(R)/(E). An appeal must be in writing and include the grounds for the appeal. It will not be sufficient for a complainant to ask for a re-consideration of the original complaint. The complainant must provide some reasons why they consider the decision to be incorrect or unfair.
- The decision of the Vice-Chancellor is considered to be final.

Responsibility

Manager Research Ethics and Compliance Unit
Chair and Deputy Chair, MUIBC
Heads of Academic Units
DVC(R)/(E)
Vice-Chancellor

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8. Research misconduct

- Chapter 2 of the Criminal Code applies to all offences against the Gene Technology Act meaning that an individual convicted of an offence against this Act will incur a penalty not exceeding that specified in the relevant section or subsection.
- Regardless of whether a successful conviction is recorded, a breach of the Gene Technology Act or these procedures may be referred to be considered under the [Monash University Research Misconduct Procedures](#).

Responsibility

MUIBC Chair
DVC(R)/(E)

Responsibility for implementation	All Monash University staff, students and visitors on Australian campuses MUIBC members, Chair, Deputy Chair and Secretary Departmental Biosafety Officers Head of Academic Units DVC(R)/(E) Vice-Chancellor Manager Research Ethics and Compliance Unit
Status	New
Approval Body	Name: Academic Board Meeting: 6/2009 Date: 25-November-2009 Agenda item: 17.1.3
Definitions	Gene technology: any technique for the modification of genes or other genetic material, but not including sexual reproduction, homologous recombination or random mutation. Genetically Modified Organism (GMO): an organism that has been modified by gene technology, or 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. Dealing: conducting an experiment with a GMO; to make, develop, produce or manufacture a GMO; to breed, propagate, grow, culture or raise a GMO; or to import or store a GMO. Physical Containment Facility (PC1-4): The Office of the Gene Technology Regulator (OGTR) has adopted this four-tier classification system based on Australian and New Zealand Standards 2982.1 and 2243.3. Dealings must be conducted in a facility certified by the OGTR at a level appropriate to the potential risk posed by the dealing. (Note: PC4 is not applicable in the Monash context.)

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Legislation Mandating Compliance	
Related Policies	
Related Documents	