Research Involving Genetically Modified Organisms (GMOs) Policy process

Objective: To ensure safe and responsible research and teaching practices involving genetically modified organisms (GMOs) consistent with institutional policy, legislation and guidelines.

Scope: This process applies to all research conducted by RMIT researchers unless appropriate approval has been gained from another body.

Definitions:

The Act: *The Gene Technology Act 2000* (Cth).

Adverse Event: Any adverse event or incident related to research involving GMOs, including but not limited to unapproved use of gene technology, spill or release of a GMO outside of a certified facility.

The Animal Code: *The Australian Code for the Care and Use of Animals for Scientific Purposes* under Part 3 of *The Prevention of Cruelty to Animals Act 1986* and *Regulations 1997*.

AEC: An Animal Ethics Committee is a committee constituted in accordance with *The Australian Code for the Care and Use of Animals for Scientific Purposes*.

Certified Facility: See Physical Containment Facility.

Chairperson: The Chairperson of the RMIT Institutional Biosafety Committee.

Code: *The Australian Code for the Responsible Conduct of Research*.

Committee: The RMIT Institutional Biosafety Committee (IBC).

Dealing: To conduct experiments with a GMO; to make, develop, produce or manufacture a GMO; to breed, propagate, grow, raise or culture a GMO; to import, transport or dispose of a GMO; to 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.

Deputy Chairperson: The Deputy Chairperson of the RMIT Institutional Biosafety Committee

Designated Person: the person performing the role of the Designated Person as defined in the Code. The Executive Director, Research Office is the Designated Person for RMIT, as nominated by the Vice-Chancellor.

DIR: **Dealing involving Intentional Release** of GMOs into the environment, which takes place outside of containment facilities. DIRs require a licence from the OGTR.

DNIR: **Dealings Not Involving Intentional Release** of GMOs into the environment are dealings with GMOs in contained facilities, which do not meet the requirements for exempt or NLRD dealings (higher risk). DNIR classes are outlined in Schedule 3 Part 3 of the Gene Technology regulations and include organisms that are pathogenic or that encode high risk pathogen genes, toxins, oncogenic modifications or an immuno-modulatory modification. DNIRs will be approved by the Committee and licenced by the OGTR.

Exempt Dealings are well understood permissible dealings of very low risk undertaken in a PC1 certified facility, or other facility that meets the requirements specified by the Office of the Gene Technology Regulator (OGTR). Exempt dealings will not involve the release of the organism into the environment.

External Approvals: An approval to carry out research involving genetically modified organisms granted by an institution that is not RMIT University.

External Researchers: A researcher from an institution that is not RMIT University.

Facility Manager: The person(s) responsible for the day to day running and activities of an RMIT Physical Containment (PC) facility.

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.

GMO: Genetically Modified Organism is an organism (i.e. plant, animal or microorganism) in which the genetic material (DNA) has been modified by gene technology (see definition above), excluding any item mentioned in Schedule 1 of the Regulations.

IBC: Institutional Biosafety Committee is a committee constituted in accordance with the OGTR *Guidelines for Accreditation of Organisations*.

Licenced Dealing: Any dealing involving a GMO which is licenced by the OGTR, including DNIRs and DIRs.

Licence Holder: An individual named on a licence for a dealing which has been licenced by the OGTR.

NLRD: Notifiable Low Risk Dealings are those of intermediate risk level and require the work to be conducted in facilities certified to PC1, PC2 or PC 3. These dealings require assessment and approval by the IBC.

OGTR: Office of the Gene Technology Regulator is established within the Australian Government Department of Health to provide administrative support to the Gene Technology Regulator in the performance of his functions under the Gene Technology Act 2000. The OGTR provides technical and regulatory support and guidance to institutions undertaking research and teaching activities involving GMOs, and also monitors and enforces compliance with the Act.

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 protect the safety of people working with GMOs inside the facility.

Secretary: The Secretary to the RMIT Institutional Biosafety Committee.

The Regulations: *The Gene Technology Regulations 2001* (Cth).

Process steps:

1. Institutional biosafety at RMIT

1.1. The RMIT Institutional Biosafety Committee (the Committee) reviews, approves and monitors all use of GMOs at RMIT. Any GMO (regardless of origin) can only be used in teaching or research with explicit Committee approval, or acknowledgement, as appropriate. Where required a licence from the OGTR will also be obtained (see Section 2.3).

1.2. RMIT University provides professional development, resources, processes and infrastructure that support researchers to know when they require institutional biosafety approval, and to gain and conduct research in line with institutional biosafety approval and with relevant codes, legislation and RMIT policy.

1.3. In Australia, RMIT researchers will remain compliant with the Act and Regulations at all times, including when at other institutions. While outside Australia, RMIT staff members will remain compliant with the Act and Regulations where possible. For advice on this, contact the Secretary.

2. Gaining institutional biosafety approval at RMIT

2.1. All dealings will be approved or acknowledged (as appropriate) by the Committee, before any work with GMOs starts. Researchers will apply for approval or licences using the processes outlined below:

2.2. Exempt dealing or Notifiable Low Risk Dealing (NLRD):

2.2.1. The researcher will apply using the RMIT forms available on the RMIT website;

2.2.2. The researcher will submit the application electronically to the Secretary by the closing date prior to the Committee meeting date. Applications will be held over to the following meeting if they are late or fail to meet any other requirements;

2.2.3. The IBC reviews the applications and either:

2.2.3.1 Provides approval; or,

2.2.3.2. Requests minor or major amendments to the application, for approval; or,

2.2.3.3. Requires resubmission.

2.2.4. NLRDs once approved have a maximum approval period of five years from the date of approval. There is no minimum or maximum approval period for exempt dealings.

2.3. Licenced Dealing:

2.3.1. The researcher will apply using the application form provided on the OGTR website.

2.3.2. The researcher will submit any application electronically to the Secretary by the closing date prior to the IBC meeting date. Applications will be held over to the following meeting if they are late or fail to meet any other requirements.

2.3.3. The IBC reviews the applications and either:

2.3.3.1. provides preliminary approval (Licenced Dealings will be approved by the OGTR);

2.3.3.2. provides preliminary approval subject to minor or major amendments to the application (Licenced Dealings will be approved by the OGTR); or

2.3.3.3. requires resubmission.

2.3.4. When Licenced Dealings have preliminary approval from the IBC, the Secretary submits them, in consultation with the researchers, to the OGTR for final approval.

2.3.5. Licenced dealings are subject to the approval period specified by the OGTR and any additional conditions of approval as set by the OGTR.

2.4. Where GMO research involves animals, the researcher will also:

2.4.1. Clearly detail the involvement of GM animals or animals exposed to other GMOs in the IBC application form;

2.4.2. Gain approval from the RMIT AEC, in accordance with the RMIT Animal Ethics Process, before starting any research; and

2.4.3. Conduct the research in line with:

2.4.3.1. *The Guidelines for the Generation, Breeding, Care and Use of Genetically Modified and Cloned Animals for Scientific Purposes (2007)*;

2.4.3.2. State and Federal animal welfare legislation;

2.4.3.3. IBC approval; and,

2.4.3.4. AEC ethical approval.

2.5. Multi-Centre Research

2.5.1. Where a planned project involves researchers from RMIT University and other collaborating institutions (including within Australia and overseas), researchers will notify the IBC and provide copies of any relevant documentation requested. A clear plan of the respective institution's responsibilities will be formally documented through a formal exchange of letter/s between the institutions.

2.5.2. Where RMIT is responsible, in part or full, for the research and where the planned project also involves researchers from other institutions (including within Australia and overseas) researchers will:

2.5.2.1. Submit an application to the Committee for review and approval (see Section 2);

2.5.2.2. Ensure a clear plan of the respective institution's responsibilities is documented through a formal exchange of letter/s between the institutions; and

2.5.2.3. Notify the Committee and provide copies of any relevant documentation requested.

2.5.3. Where the research is the sole responsibility of another institution (i.e. an external project) and the planned project also involves researchers from RMIT:

2.5.3.1. The Committee will not review the research provided another IBC has reviewed and approved the dealings.

2.5.3.2. RMIT researchers will submit a copy of the application approved by the other institution's IBC to the Secretary and receive acknowledgement prior to any staff member working on an external project.

2.5.3.3. The Committee will note any approvals from external IBCs and assess compliance with the relevant legislation and regulations, and institutional policy.

3. Review process

3.1. The Committee reviews all applications for Exempt, Notifiable Low Risk Dealings and Licenced Dealings and applies the set of principles 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.

3.2. The Committee will inform the researchers of the outcome of the review in a timely manner.

4. Variations to a dealing

4.1. Researchers can apply for a variation to an exempt dealing or a NLRD by submitting an appendix to their original dealing outlining the variation to the Secretary, for approval and/or acknowledgement as appropriate by the Committee.

4.2. Researchers will gain Committee approval and/or acknowledgement for a variation prior to implementing the change.

4.3. Licenced dealings can only be varied with the prior approval of the OGTR. Researchers will contact the Secretary who will liaise with the OGTR on their behalf.

5. Reporting

5.1. Researchers will submit an annual report at the end of each calendar year for the life of the project.

5.2. The Principal Investigator will submit a final report within six months of the end of the approval period.

5.3. Reports will use the RMIT templates, available on the RMIT website.

5.4. Reports will detail how the research involving GMOs complied with the Act and Regulations over the reporting period, and detail any non-compliance and/or adverse incidents, including unintentional release or spills of GMO material.

5.5. The Committee will review all annual and final reports. The Secretary will inform researchers if the reports have been accepted or if more information is needed.

6. Adverse events

6.1. Any adverse event will be reported to the Committee (through the Secretary) and to the relevant Facility Manager where appropriate, as soon as it is discovered.

6.2. The researcher will provide an Adverse Event Report that details the adverse event and any action taken that has or will be taken in relation to the event and/or to prevent a recurrence.

6.3. This report will be reviewed by the Committee at the next scheduled meeting. The Committee may require researchers to provide further information and/or carry out further actions. Where appropriate and/or as required, the Committee will notify the line manager, licence holder, licence holder, and/or the OGTR.

6.4. Where an adverse event involves any real or suspected release, including spills, of genetically modified materials or organisms outside of a certified facility not approved by the OGTR, the researchers will report this to the Committee via the Secretary and the Committee will review it as

soon as reasonably possible. The Committee will report any real or suspected unintentional release of GMOs to the OGTR as soon as reasonably possible.

7. Monitoring approval

7.1. The Committee will monitor all dealings for research involving GMOs at RMIT through inspections and reviewing records and reports (including annual and final reports, review of Adverse Incident Report forms).

8. Suspension and/or withdrawal of approval

8.1. The Committee may suspend or withdraw approval for any project when:

8.1.1. A GMO or gene technology is used in a manner inconsistent with the approved protocol. In this instance the Chairperson or Deputy Chairperson may require that the activities (either the specific activity in question or the full project) cease immediately; or

8.1.2. The approved protocol is no longer consistent with the Act or Regulations; or

8.1.3. The researchers do not fulfil their reporting requirements; or

8.1.4. Any other instance of non-compliance with the Act or Regulations, which the Committee deems of sufficient nature to warrant suspension or withdrawal of approval for a project.

8.2. Where the Committee has suspended or withdrawn approval for a project, the Chairperson will notify the line manager, and may also notify the OGTR and other parties as appropriate.

8.3. In reviewing cases of non-compliance, the Committee may refer the matter to the institution (the Designated Person at RMIT), or the OGTR as appropriate, for consideration. Where required, the Committee will refer a matter to the institution (the Designated Person at RMIT) for consideration in line with the Research misconduct process.

9. Physical containment facilities

9.1. All facilities seeking certification as a Physical Containment (PC) facility will meet current OGTR Guidelines for the Certification of Physical Containment Facilities (level and type), as well as current Australian/New Zealand Standards.

9.2. Committee members will conduct inspections and complete the appropriate application checklist for the PC facility type and level. The PC Facility Manager / Supervisor or a suitable nominee will also attend inspections and it is advisable that a researcher intending to conduct dealing(s) within the facility be present to answer questions. All issues will be resolved before the application for certification proceeds.

9.3. The Facility Manager / Supervisor will collate any additional paperwork required for the certification application and forwarding to the Secretary. The Secretary will send completed applications to the Deputy Vice Chancellor (Research & Innovation) to be authorised prior to submission to the OGTR. Following submission, the Secretary will liaise with the OGTR to ensure that any outstanding certification requirements are resolved.

9.4. Once certification is granted by the OGTR, the Committee will retain a copy of the certification on record and forwards the certification and signage to the Facility Manager / Supervisor.

9.5. The Committee will inspect OGTR certified physical containment level 2 (PC2) or higher facilities at least every 12 months. The University (through the Secretary) will maintain inspection reports for a minimum of 5 years and provide these to the OGTR on request.

9.6. Access to OGTR certified facilities is restricted to authorised persons who have completed the relevant RMIT University training. Unauthorised persons may only enter certified facilities with the permission of the Facility Manager / Supervisor and will not conduct any dealings in certified facilities. Unauthorised persons may include contractors, maintenance staff and visitors.

10. Complaints

10.1. Complaints regarding research involving GMOs

10.1.1. Staff, students, members of the public or any other concerned persons may make a complaint concerning the research involving GMOs or gene technology at RMIT.

10.1.2. These complaints will be forwarded to the Secretary. The Research Office will respond appropriately.

10.2. Complaints concerning the use of GMOs in a particular research project

10.2.1. Staff, students, members of the public, or any other concerned persons may make a complaint concerning the use of GMOs or gene technology in an RMIT dealing.

10.2.2. These complaints will be forwarded to the Secretary.

10.2.3. Where there are ongoing safety issues and/or non-compliance with the Act or Regulations that present significant risk to health and safety or humans, animals or the environment, the institution will ensure researchers cease activities and the Committee may suspend or withdraw approval;

10.2.4. The Research Office will acknowledge receipt notify and consult the Chairperson, and take one or more of the following steps:

10.2.4.1. Where the complaint relates to activities that would normally require RMIT Committee approval, refer the complaint to the RMIT Committee to investigate in accordance with the Act and Regulations;

10.2.4.2. Where the complaint relates to activities that would normally require a licence, refer the complaint to the OGTR;

10.2.4.3. Where the complaint raises the possibility of research misconduct, or a breach that is not related to ethics approval, refer the complaint to the Designated Person who will handle the complaint in line with the Research Misconduct Process [hyperlink TBC];

10.2.4.4. Where the complaint alleges misconduct that is not research related, refer it onto the appropriate institutional process;

10.2.4.5. Dismiss the complaint and provide reasons for dismissal.

10.2.5. The Research Office will update the complainant and other relevant parties, including the OGTR, as appropriate and in a timely manner.

10.3. Complaints regarding a decision of the Committee

10.3.1. Submit the complaint to the Director of Research Integrity, Governance and Systems in writing.

10.3.2. The ultimate decision regarding the acceptability and classification of a dealing involving GMOs lies with the Committee.

10.4. Complaints regarding the operation of the Committee

10.4.1. Make the complaint in writing to the Director of Research Integrity, Governance and Systems, who will notify the Committee and the Research Office.

10.4.2. Where communication between the Committee and the complainant cannot resolve the complaint, the Committee will form a Subcommittee to investigate the facts of the complaint, write a report, and make recommendations to both parties and inform the Research Office.

10.4.3. Where the Subcommittee cannot resolve the complaint, the Deputy Vice Chancellor Research & Innovation will appoint a person external to the Committee (the Designated Person or nominee) will review the operational process followed by the Committee, and report findings and recommendations to the Research Office and Committee. The Research Office and the Committee will consider the findings and recommendations of this review.

Related policy: Research Policy

Supporting documents: Research involving GMOs complaints flowchart (PDF 201KB 1p)

Research involving GMOs at RMIT

Cross-referenced to:

- Animal ethics process
- Research misconduct process
- Guidelines for the transport, storage and disposal of GMOs
- Gene Technology Act 2000
- Gene Technology Amendment Act 2007
- Gene Technology Regulations 2001

Feedback link: Policy@rmit.edu.au

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