

Low Risk Genetically Modified Dealings Procedure

Section 1 - Purpose and Scope

(1) This Procedure outlines requirements at The University of Queensland (UQ) for conducting work (a 'dealing') with genetically modified organisms (GMOs) that are classified as Exempt Dealings or Notifiable Low Risk Dealings (NLRD) under the [Gene Technology Act 2000](#). The definition of a 'dealing' for the purposes of this Procedure is provided in the appendix. This Procedure supports UQ's [Biosafety Policy](#) and outlines the requirements UQ workers must meet to comply with gene technology regulation.

(2) This Procedure applies to all staff, students, visitors, volunteers, and contractors (UQ workers) conducting dealings with GMOs at UQ's St Lucia, Gatton, and Herston campuses and associated working areas (including Long Pocket, Greenslopes Hospital, and the Translational Research Institute).

(3) This Procedure should be read in conjunction with the UQ [Biosafety Policy](#) that apply for genetically modified (GM) dealings.

Context

(4) The Australian Government regulates GMOs under the [Gene Technology Act 2000](#), which provides that all dealings with GMOs are prohibited unless they are classified otherwise. The [Office of the Gene Technology Regulator](#) (OGTR) administers requirements of [the Act](#) and classifies materials based on risk to the health and safety of people and the environment.

(5) Exempt Dealings and NLRDs are categories of dealings with GMOs that have been assessed by the OGTR as posing very low to low risk provided certain risk management conditions are met. It is a legislative requirement that Exempt Dealings and NLRDs must not involve an intentional release of a GMO into the environment.

(6) The [Gene Technology Regulations 2001](#) ([the Regulations](#)) provide descriptions of Exempt Dealings, NLRDs and host/vector systems that have been classified by the OGTR. UQ workers should refer to [the Regulations](#) to determine the classification of the proposed dealing.

(7) Further information about the regulation of GMOs in Australia is available from the Health, Safety and Wellness Division's Biosafety Advisors or the [OGTR's website](#).

Section 2 - Process and Key Controls

(8) UQ workers must comply with the following measures when conducting dealings with GMOs at UQ:

- a. Before dealing with GMOs, UQ workers must follow appropriate risk management procedures, and be properly trained (UQ online Biosafety training and specific training determined by the supervisor) and assessed competent by their supervisor to work with GMOs.
- b. Undergraduate students, volunteers and visitors must always be supervised while undertaking a dealing with a GMO or GM material.
- c. Applications for Exempt Dealings and NLRDs with GMOs must be approved by UQ's Institutional Biosafety

Committee (IBC) to ensure that the applications comply with the relevant classification criteria.

- d. Exempt Dealings and NLRDs with GMOs at UQ must be performed in a level 1 or higher Certified Physical Containment facility (PC1), as appropriate to the risk group classification of the material.
- e. Chief Investigators are primarily responsible for the oversight of Exempt Dealings and NLRDs with GMOs at UQ, including the application process and ongoing management of the dealing.

Section 3 - Key Requirements

Training and Risk Management

(9) Before conducting any dealing with GMOs, UQ workers must:

- a. undertake the appropriate induction training as required (refer to the [HSW new worker checklist in Workday](#));
- b. complete a risk assessment(s) and familiarisation with any standard operating procedures;
- c. comply with the conditions stipulated in the IBC's approval of the dealing.

Approval Process

(10) Before undertaking any dealing with a GMO that is considered an Exempt Dealing or a NLRD, the work must be approved by the IBC. Applications must be made to the IBC by the Chief Investigator using the Lab Activity Application Register in [UQSafe](#).

(11) The Chief Investigator must provide sufficient information within the application to allow the IBC to determine whether the proposed dealing meets the relevant classification criteria.

Reporting Breaches

(12) Chief Investigators and UQ workers are responsible for monitoring all aspects of an Exempt Dealing or a NLRD they are authorised to undertake. Any actual or potential breaches of conditions associated with the use, storage or handling of GMOs should be reported as soon as practicable to UQ Biosafety Advisors (biosafety@uq.edu.au).

Conducting Dealings with GMOs

(13) In conducting dealings with GMOs, Chief Investigators must:

- a. Ensure that the dealings with GMOs comply with the conditions of the IBC's approval and are conducted in a certified Physical Containment facility appropriate for the risk group of the material being used (i.e. PC2 for risk group 2 material).
- b. Ensure that the dealings with GMOs are within the scope of the IBC approval, and if any deviation is anticipated, new approvals sought before attempting such work.
- c. Regularly monitor and review the dealings until they are closed by the Chief Investigator, a UQ Biosafety Advisor or the IBC (to close a dealing, all materials must have either been transferred to another dealing, reviewed, and assigned a new IBC number for continuation (if required) or destroyed).
- d. Ensure correct storage of GMOs.
- e. Inform UQ's Biosafety Advisors if movement to another facility not listed on the approval is required.

Section 4 - Roles, Responsibilities and

Accountabilities

Institutional Biosafety Committee

(14) The IBC will undertake duties in accordance with its Terms of Reference and the [Biosafety Policy](#). The IBC's responsibilities include:

- a. Assessment and approval of applications for dealings classified as Exempt Dealings and NLRDs by [the Regulations](#).
- b. Assisting Chief Investigators determine classification of GMO dealings.
- c. Providing UQ workers with education, information, and support to enable them to understand their biosafety compliance obligations at UQ.

Health, Safety and Wellness Division

(15) The Health, Safety and Wellness Division is responsible for:

- a. Providing UQ workers with education, advice and support regarding OGTR requirements and gene technology regulatory compliance obligations at UQ.
- b. Assessing whether Organisational Units and UQ workers can demonstrate compliance with this Procedure and that any compliance issues identified are rectified in a timely manner.

(16) Biosafety Advisors within the Health, Safety and Wellness Division are responsible for:

- a. Advising workers about specific gene technology matters affecting UQ, including workplace safety obligations and regulatory compliance.
- b. Reporting to or advising UQ's IBC on gene technology matters as required.
- c. Liaising with the OGTR with respect to UQ's gene technology and GMO dealings compliance obligations (including hosting regulator site visits or inspections).

Heads of Organisational Units Authorised to Undertake Dealings

(17) Heads of Organisational Units that undertake dealings with GMOs must work with Chief Investigators to ensure containment facilities are compliant with OGTR requirements, including:

- a. facilities appropriate for the type of work are available and maintained in compliance with the relevant legislative requirements (e.g. PC2 certified facilities maintained to OGTR certification requirements, including funding and arrangements for maintenance, routine testing and servicing); and
- b. any work with material meeting Exempt Dealing or NLRD classification is conducted in compliance with requirements detailed in [the Act](#) and [Regulations](#), associated facility certification guidelines or IBC approvals (e.g. GM work has appropriate approvals in place before commencing, all UQ workers have completed appropriate training prior to commencing work).

Chief Investigators

(18) Chief Investigators are responsible for the ongoing monitoring, management and oversight of Exempt Dealings and NLRDs, and must ensure:

- a. Dealings are conducted in appropriate facilities and that the facilities are tested, serviced, and maintained to comply with OGTR requirements.
- b. An Exempt Dealing or NLRD approved by the IBC is in place prior to commencing work with the GMO.

- c. Exempt Dealings and NLRDs are reviewed and extended or closed where necessary.
- d. Records are maintained in accordance with facility certification or IBC approval requirements.
- e. UQ workers that handle, store or use GMOs:
 - i. are trained in accordance with [OGTR](#) requirements;
 - ii. comply with all conditions of approval from the IBC and/or for the use of the containment facility, including supervision of any classes of person not authorised by the IBC to work unsupervised with a GMO (including undergraduate students, visitors, and volunteers).

UQ Workers

(19) All UQ workers undertaking Exempt Dealings or NLRDs with GMOs at UQ must comply with this Procedure, understand, and comply with any additional requirements specified by [OGTR](#), and ensure they are:

- a. following the requirements for the facility being worked in (i.e. complete relevant training, comply with PPE requirements etc.); and
- b. aware of any approvals that are in place for the work they are conducting.

(20) UQ workers handling, using, or storing GMOs at locations external to UQ, must comply with the local procedures and requirements of the external organisation.

Section 5 - Monitoring, Review and Assurance

Compliance

(21) UQ Biosafety Advisors will provide ongoing monitoring and review of UQ's biosafety systems and controls on behalf of the IBC. This includes annual audits and inspections of [OGTR](#) certified facilities where Exempt Dealings and NLRDs are undertaken, renewal of any associated facility certifications, and renewal of any associated licences. UQ Biosafety Advisors will review this Procedure as required to ensure it remains current and accurately reflects regulatory requirements.

Non-compliance

(22) UQ workers and Chief Investigators that do not comply with this Procedure will be subject to corrective actions from the IBC and/or the Health, Safety and Wellness Division, and suspension of work if conditions are not met.

(23) UQ may be subject to corrective actions or notices issued by the [OGTR](#) to suspend work that does not comply with regulatory requirements.

Section 6 - Recording and Reporting

(24) Chief Investigators must ensure that the record-keeping requirements of approved Exempt Dealings and NLRDs are met.

(25) Information collected from Chief Investigators' applications to the IBC may be provided to the [OGTR](#) for auditing purposes if required.

(26) UQ Biosafety Advisors will report outcomes of audits of [OGTR](#) certified facilities where Exempt Dealings and NLRDs are undertaken to the IBC on a regular basis (e.g. at each scheduled IBC meeting) and the IBC will report any non-compliances or potential breaches to UQ Senior Management and for the relevant area.

(27) The IBC chair and the Director, Health Safety and Wellness are responsible for reporting any matters required by [the Act](#) or [Regulations](#), approvals, or licences to the OGTR.

Section 7 - Appendix

Definitions, Terms, Acronyms

Terms	Definitions
Authorised Classes of Persons	For the purposes of undertaking a dealing with a GMO or GM material, the following classes of persons must be supervised at all times while working – undergraduate students, volunteers, visitors who have not completed online biosafety training.
Chief Investigator	For the purposes of this Procedure includes Supervisors, Managers and academic principal advisors that are conducting research at UQ and hold an academic or research appointment.
Dealing	<p>In relation to a GMO, 'dealing' is defined in the Act as meaning:</p> <ul style="list-style-type: none">- conduct experiments with the GMO;- make, develop, produce or manufacture the GMO;- breed the GMO;- propagate the GMO;- use the GMO in the course of manufacture of a thing that is not the GMO;- grow, raise or culture the GMO;- import the GMO;- transport the GMO;- dispose of the GMO;- possess, supply or use the GMO for the purposes of, or in the course of, any of the above.
Exempt Dealing	A category of Dealing with GMOs that has been assessed over time as posing a very low risk (i.e. contained research involving very well understood organisms and processes for creating and studying GMOs).
GMO	Genetically Modified Organism.
IBC	UQ's Institutional Biosafety Committee.
Notifiable Low Risk Dealing	A category of Dealing with GMOs that has been assessed over time as posing a low risk (i.e. contained research not released into the environment) provided certain risk management conditions are met.
OGTR	Office of the Gene Technology Regulator (Australian Government).
UQ Workers	<p>For the purposes of this Procedure includes:</p> <ul style="list-style-type: none">- UQ staff, including continuing, fixed-term and casual staff;- contractors, subcontractors and consultants;- students enrolled at UQ, including post graduate researchers, Higher Degree by Research students and undergraduate students;- visiting academics and researchers;- visiting research students; and- volunteers engaged by UQ that may be required to handle OGTR regulated material.

Status and Details

Status	Current
Effective Date	21st December 2022
Review Date	21st December 2027
Approval Authority	Director, Health Safety and Wellness
Approval Date	21st December 2022
Expiry Date	Not Applicable
Policy Owner	Jim Carmichael Director, Health Safety and Wellness
Enquiries Contact	Health, Safety and Wellness Division