Working with Gene-Edited Material Procedure

Section 1 - Purpose and Scope

(1) This Procedure outlines requirements at The University of Queensland (UQ) for conducting work with gene-edited material following release from genetically modified (GM) dealing conditions. The definitions of "gene-edited material" and "GM dealing conditions" for the purposes of this Procedure are provided in the appendix.

(2) This Procedure applies to all UQ workers – including staff, students, visitors, volunteers and contractors – working with gene-edited material following release from GM dealing conditions at UQ campuses, sites and facilities. Gene-edited material created in UQ owned or controlled facilities, or used by UQ workers following release from GM dealing conditions, at other non-UQ sites (for example Department of Agriculture, Fisheries and Forestry or CSIRO owned facilities) are also subject to the requirements of this Procedure.

(3) This Procedure supports UQ's Biosafety Policy should be read in conjunction with other relevant procedures that apply to GM dealings (e.g. Low Risk Genetically Modified Dealings Procedure).

Context

(4) The Australian Government regulates genetically modified organisms (GMOs) under the Gene Technology Act 2000, which states 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) The Gene Technology Regulations 2001 provide descriptions of Exempt Dealings, Notifiable Low Risk Dealings and host/vector systems that have been classified by the OGTR. The Regulations also provide descriptions of organisms that are not considered genetically modified including those that were generated through gene modification techniques (Schedule 1) (i.e. gene-edited material released from GM dealing conditions). UQ workers should refer to the Regulations to determine the classification of the proposed dealing.

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

Section 2 - Process and Key Controls

(7) UQ workers must comply with the following measures when working with gene-edited material at UQ:

a. Before dealing with GMOs or gene-edited material released from GM dealing conditions, 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 be supervised at all times by a UQ worker authorised by UQ's Institutional Biosafety Committee (IBC) while undertaking a dealing with a GMO or GM material.
c. Before work with gene-edited material can be released from GM dealing conditions, approval must be obtained from UQ's IBC to ensure the proposal complies with the relevant classification criteria.
d. Chief Investigators are primarily responsible for the oversight of work with gene-edited material released from

GM dealing conditions at UQ, including the application process and ongoing management of the dealing.

Section 3 - Key Requirements

Training and Risk Management

(8) Before conducting any work with gene-edited material released from GM dealing conditions, UQ workers must:

a. undertake the appropriate induction training as required (refer to the staff health and safety training and induction website and the Inductions and Training Needs Assessment Checklist);
b. complete a risk assessment(s) and familiarisation with any standard operating procedures;
c. obtain approval from the UQ IBC (refer to clauses 9-11 of this Procedure); and
d. comply with the conditions stipulated in the IBC's approval of the work.

Approval Process

(9) Work with gene-edited material released from GM dealing conditions, as defined in this Procedure, is not permitted at UQ without prior approval from the UQ IBC. Applications to work with gene edited material released from GM dealing conditions must be made to the IBC by the Chief Investigator using the Lab Activity Application Register in UQSafe.

(10) 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. Specific instructions on the information to be provided with the application is provided in the appendix.

(11) All approved work with gene-edited material released from GM dealing conditions must comply with any conditions stipulated in the IBC's approval of the work.

Compliance with Gene-edited Material Requirements

(12) Chief Investigators and UQ workers are responsible for monitoring all aspects of work authorised under an IBC approval to release gene-edited material from GM dealing conditions. In conducting work with gene-edited material released from GM dealing conditions, Chief Investigators must:

a. ensure that the work complies with the conditions of the IBC's approval; and
b. regularly monitor and review the work in line with good laboratory practices.

Reporting Breaches

(13) Any actual or potential breaches of conditions associated with the use, storage or handling of gene-edited material released from GM dealing conditions must be reported as soon as practicable to UQ Biosafety Advisors (biosafety@uq.edu.au).

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 to release gene-edited material from GM dealing conditions;
b. assisting Chief Investigators determine classification of work covered under this Procedure; and
c. providing UQ workers with education, information and support to enable them to understand their biosafety compliance obligations at UQ.

Chief Investigators

(15) Chief Investigators are responsible for the ongoing monitoring, management and oversight of work with gene edited material released from GM dealing conditions, and must ensure:

a. work is conducted in appropriate facilities or locations in compliance with OGTR or IBC approvals;
b. an IBC approval to release gene-edited material from GM dealing conditions is in place prior to commencing work;
c. records are maintained in accordance with IBC approval requirements and UQ's Responsible Research Management Framework Policy and Research Data Management Policy;
d. UQ workers that handle, store or use gene-edited material released from GM dealing conditions:
    i. are trained in accordance with UQ IBC requirements; and
    ii. comply with all conditions of approval from the IBC, including supervision of any classes of person not authorised by the IBC to work unsupervised with the material (including undergraduate students, visitors and volunteers); and
e. ensure the IBC's approval to release gene-edited material from GM dealing conditions is obtained prior to each release.

Heads of Organisational Units

(16) Heads of Organisational Units that undertake work with gene-edited material released from GM dealing conditions must work with Chief Investigators to ensure compliance with OGTR or IBC requirements, including:

a. ensuring any work with gene-edited material released from GM dealing conditions is conducted in compliance with requirements detailed in this Procedure and relevant IBC approvals (e.g. all work has appropriate approvals in place before commencing, all UQ workers have completed appropriate training prior to commencing work); and
b. ensuring appropriate agreements with external collaborators are in place prior to any gene-edited material released from GM dealing conditions.

UQ Workers

(17) All UQ workers working with gene-edited material released from GM dealing conditions at UQ must comply with this Procedure, understand and comply with any additional IBC requirements, and ensure they are:

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

(18) UQ workers handling, using or storing gene-edited material released from GM dealing conditions at locations external to UQ, must comply with the local procedures and requirements of the external organisation.

Health, Safety and Wellness Division

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

a. providing UQ workers with education, advice and support regarding requirements for working with gene-edited material released from GM dealing conditions and relevant regulatory compliance obligations at UQ; and
b. assessing whether Organisational Units and UQ workers are able to demonstrate compliance with this Procedure and that any compliance issues identified are rectified in a timely manner.

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

a. advising workers about specific Biosafety matters affecting UQ, including workplace safety obligations and regulatory compliance; and
b. reporting to or advising UQ's IBC on gene-edited material released from GM dealing conditions as required.

Section 5 - Monitoring, Review and Assurance

(21) UQ Biosafety Advisors will:

a. provide ongoing monitoring and review of UQ's biosafety systems and controls on behalf of the IBC; and
b. 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 UQ IBC approval to release gene-edited material from GM dealing conditions are met in accordance with UQ's Research Data Management Policy.

(25) UQ Biosafety Advisors will report outcomes of audits of IBC approvals to release gene-edited material from GM dealing conditions to the IBC on a regular basis (e.g. at each scheduled IBC meeting). The IBC will report any non-compliances or potential breaches to the relevant Deputy Vice-Chancellor, Executive Dean or Institute Director and line management for the relevant area.

(26) The Director, Health Safety and Wellness is responsible for reporting any matters required by the Act or Regulations, approvals or licences to the OGTR.

Section 7 - Appendix

Definitions

Terms	Definitions
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.

Terms	Definitions
Dealing	In relation to a GMO, 'dealing' is defined in the Act as meaning: • 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; and • possess, supply or use the GMO for the purposes of, or in the course of, any of the above.
Gene-edited Material	From the Gene Technology Regulations 2001, Schedule 1 – Organisms that are not genetically modified organisms – an organism modified by repair of single-stranded or double-stranded breaks of genomic DNA induced by a site-directed nuclease, if a nucleic acid template was not added to guide homology-directed repair.
GM Dealing Conditions	Conditions issued either by the UQ IBC or the OGTR for work with GMOs either as an Exempt or Notifiable Low Risk Dealing (see Low Risk Genetically Modified Dealings Procedure), Dealing Not for Intentional Release (DNIR) or Dealing for Intentional Release (DIR).
GMO	Genetically modified organism.
IBC	UQ's Institutional Biosafety Committee.
OGTR	Office of the Gene Technology Regulator (Australian Government).
UQ Workers	For the purposes of this Procedure includes: • staff – continuing, fixed-term, research (contingent funding) and casual staff members; • contractors, subcontractors and consultants; • visiting academics and researchers; • affiliates – academic title holders, visiting academics, Emeritus Professors, adjunct and honorary title holders, Industry Fellows and conjoint appointments; • Higher Degree by Research students; and • volunteers and students undertaking work experience.

Supporting Information for IBC Applications

(27) In order to demonstrate to the IBC that there are no transgenes present in a segregant individual, researchers will need to perform a series of experiments to the satisfaction of the IBC.

(28) Researchers should:

a. identify an endogenous gene in the plant species being analysed and design primers for PCR amplification; and
b. design primers for amplification of the Cas9 gene and the selectable marker being used.*
   It is recommended that the size of the amplicon is kept between a minimum (200-300 nt) and a maximum (1-1.5 kb).

(29) Three different genotypes should be analysed:

a. Progenitor parent(GM).
b. Segregant progeny(3 replicates).
c. Wild type(WT).

(30) Genomic DNA from the three genotypes will be purified and subjected to PCR amplification using all sets of primers for all samples. The results of the PCR should be analysed by gel electrophoresis, photographed and provided to the IBC. Gels and photos should be clear enough to be inspected by members of the IBC.

(31) The number of cycles used in the PCR is variable but it should be enough to clearly show a band on the endogenous gene lane while no band should be observed on the transgene lanes. For each segregant to be released, three individual DNA samples extracted from different tissue samples should be analysed.

(32) The expected results are detailed in the linked diagram: Expected results of genotype analysis.

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* If the GM lines have been generated using particle bombardment. At least two other genetic sequences included in the backbone of the vector should be included, one of which should be the marker used for bacterial selection.

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