Genetically Modified Organism (GMO) Project Approval Procedure

Approving Authority:	University Biosafety Committee (UBC)
Approval Date:	10 November 2017
Review Date:	2022
Procedure Adviser:	Manager – Research Ethics and Integrity
Supersedes:	This procedure supersedes the Genetically Modified Organism Project Approval Procedure 2014

Related Policies, Procedures and Forms:

Gene Technology Act 2000
Gene Technology Regulations 2001
Griffith University Code of Conduct Policy
Griffith University Health & Safety Policy
Griffith University Biosafety Committee Annual Progress Report/Final Report Form
Griffith University Biosafety Committee Exempt Dealing Evaluation Report
Griffith University Biosafety Committee NLRD Project Application Form
Office of Gene Technology Regulator DNIR Application Form
Office of Gene Technology Regulator Guidelines for Accreditation of Organisations
Office of Gene Technology Policy on Storage of Genetically Modified Organisms
Office of Gene Technology Guidelines for the Transport, Storage and Disposal of GMOs
Office of Gene Technology Licence for Storage of GMOs Application form
Office of Gene Technology IBC Evaluation form
Australian Code for the Responsible Conduct of Research

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1.0 Introduction

Best practice can be achieved when organisations regularly and routinely seek, and obtain assistance from, their properly constituted, resourced and maintained University Biosafety Committee (UBC) whose members are able to provide professional, technical and unfettered advice on risks related to the gene technology work undertaken at the organisation.

As a requirement under the Office of the Gene Technology Regulator (OGTR) Guidelines for Accreditation of an Organisation the Griffith University UBC provides advice to principal researchers and course conveners by advising them on the identification and management of the risks associated with dealings with GMOs undertaken by the organisation including the containment of GMOs and providing an interface with the OGTR.

2.0 Objective of the Approval

All dealings with GMOs must be reviewed by the UBC for the following reasons:

- To ensure correct GMO classification;
- To analyse and ensure all risks and hazards have been identified and are appropriately dealt with; and
- To ensure compliance with legislation.

3.0 Glossary

Applicant	The person who has written the application and submitted it for evaluation. It may or may not be the Principal Researcher.
Authorised Person	A person who has been delegated the authority to submit DNIR and DIR applications and variations on behalf of the University to the OGTR.
Contact	A contact person that has operational responsibility over the dealings or the facilities associated with the dealing.

Compliance Coordinator	A Health, Safety and Wellbeing Biosafety Adviser who coordinates the review and approval process within GSafe.
Lead Reviewer	A member of UBC review panel nominated as the lead reviewer by the Compliance Coordinator based on the member's technical and research experience.
Principal Researcher	The Principal Researcher (or Leader) is the person leading the project described on the application form. They are responsible for operational compliance. The Principal Researcher may be a Course Convener rather than a research staff member.
Scientific Review Panel	Internal, external and adjunct members of the UBC who have the necessary collective expertise to scientifically assess a dealing.
Technical Review Panel	Health, Safety and Wellbeing Biosafety Advisers and where applicable, the Manager, Griffith Bioscience Service Centre.
Provisional Approval	An application status indicating the dealing has been approved by the review panel and UBC, but work involving GMOs may not commence until all participants have declared *in writing* that they have read and understood all approval and licence conditions.

4.0 Scope

This procedure applies to the review of applications to undertake dealings with GMOs at Griffith University.

5.0 Approval Process

The approval process is designed to evaluate applications relative to the *Gene Technology Regulations 2001* (the Regulations) and is based on the dealing types described in the Regulations;

- Exempt Dealing (ED)
- Notifiable Low Risk Dealing (NLRD)
- Dealing Not Involving an Intentional Release (DNIR)
- Dealing Involving Intentional Release (DIR)

Applications are evaluated by a Scientific and Technical Review Panel via an online process in the Lab Activity Register in GSafe. The recommendation of the panel is ratified at the next UBC meeting.

A summary table of the review process, Table 1, can be found in Appendix 1.

5.1 Review Panel Selection

The Review Panel members assigned to review an application are selected based on their availability and area of expertise. The size and composition of the review panel varies based on the type of dealing. A reviewer external to the university is included for the review of all dealing types other than EDs.

5.2 Timing of Review Process

Reviewers are asked to provide a response within 7 working days for each review round for ED and NLRD applications, resulting, on average, in a 4 week approval process.

For DNIRs, reviewers are asked to provide a response within 14 working days for each review round, resulting in a 4-8 week approval process. Once the UBC has approved a DNIR application it will be sent to the OGTR. The OGTR will evaluate the application and issue an approval or reject the application within 90 working days. Note: Any time the OGTR request further information on the application the time counter will pause while they wait for a response from the applicant.

5.3 New Applications

For all dealings the evaluation process is similar. The steps involved in the review process are outlined below, with notes for DNIR and DIR projects written in *italics*.

5.3.1 The applicant will log into the GSafe system and navigate to the Lab Activity Register. Once there they should click on the "New" icon and complete the appropriate ED, NLRD or DNIR project application form and submit the application.

5.3.2 The Compliance Coordinator will carry out a completeness check and assign a UBC Identifier to the application. A review panel is then selected by the Compliance Coordinator. The applicant may track the processing status of the application via the Lab Activity Register. The dealing identifier format and the composition of the review panel is described in Table 1.

5.3.3 The application is distributed electronically via a blind process to the review panel members.

At this stage the review panels for DNIR and DIR applications are also advised they may request a face to face meeting of the review panel.

5.3.4 Recommendations and or requests for further information from review panel members are returned to the Compliance Coordinator. The review panel members are required to contact the Compliance Coordinator if further time is needed to complete the review.

5.3.5 If required, requests for further information will be collated by the Compliance Coordinator and shared with the applicant via GSafe.

5.3.6 If the panel requires additional information from the applicant at the end of two review rounds, the Lead Reviewer will liaise with members of the review panel and the applicant until all comments are addressed and a decision can be made regarding approval.

If the application is a DNIR or DIR and the Review Panel is satisfied with the application, the application, signed by the project supervisor, will be provided to an Authorised Person for final review, signing by the Chair and submission to the OGTR.

The OGTR must make decisions about licence applications within a specified number of working days. If the OGTR sends a query to an applicant the time counter stops until the applicant submits a reply. The time frames are:

- *90 days for a DNIR: 90 working days*
- *255 days for DIRs that are not limited and controlled release applications:*
- *150 working days (or 170 working days if a significant risk is identified) for DIRs that are limited and controlled release applications.*

5.3.7 Once the review is completed the application can proceed to approval. If no declaration is required (EDs) the dealing will be approved, the approval conditions will be made available on the Approval Conditions tab and all project participants will be notified via an email from the GSafe system.

If a declaration is required the application will be Provisionally Approved. All participants will be asked to view the approval conditions available as an attachment on the electronic application form in GSafe and either *Accept* or *Decline* the approval conditions and the declaration. The project will only be approved and work allowed to commence once all participants *Accept* the declaration and approval conditions.

For DNIRs and DIRs, the OGTR will provide a Licence to the University including a list of licence conditions. The participants on the project must Accept these conditions along with those on the Approval from the UBC prior to commencing any work.

Note: The UBC will provide a list of NLRDs approved by the Committee to the OGTR on an annual basis. The list of NLRDs held by the OGTR may be viewed by the public via the OGTR website.

5.4 Amendments or Variations to Approved Dealings

During the conduct of an approved project, there may be a requirement to amend or modify the project. Dealings may be varied under the following circumstances:

- the addition or removal of facilities or personnel, and;
- to add or delete a host/vector system, parent organism or trait providing it does not change the original project classification, scope of the project or increase risk.

The OGTR allows DNIRs and DIRs to be varied, but not EDs and NLRDs. As such, the process of updating or changing an ED or NLRD effectively closes the existing dealing and creates a new one. However, the process of varying an approved application, be it an ED, NLRD, DNIR or DIR is similar

to the submission of a new application, with adjustments to the process based on the nature of the requested changes.

5.4.1 The applicant should navigate to the Approved dealing they wish to vary within the GSafe Lab Activity Register. After opening the record, they should click on the Variation button to generate a pre-approval copy of the approved application.

The new application will have a link that will take them back to the parent application. The applicant should make the desired amendments and submit it for review. Changes to the content of text boxes should be done using some form of text differentiation, *e.g.* bold, underlining, different coloured font, so the changes can easily be identified.

5.4.2 The Compliance Coordinator will examine the variation to identify the changes to the dealing. Where the only changes to an ED or NLRD involve personnel, facilities or transport of materials, the Compliance Coordinator will request a review by the Technical Review Panel only.

If the changes appear to be a minor change in project scope, or a change to parent organisms or modified gene, a Scientific and Technical Review Panel will be required and the variation will undergo the same review process as described in 5.3 New Applications.

5.4.3 The panel will review the variation application using the same time frames as described in Section 5.3.

5.4.4 If the Compliance Coordinator or review panel identifies that the variation significantly changes the project scope, GMO classification, or uses organisms in a higher Risk Group, or another change gives rise to additional risks, the applicant will be required to submit a new project application.

5.4.5 If the review panel is satisfied that the project variation is consistent with the two dot points listed at the start of Section 5.4, they may recommend approval of the variation. The approval process will follow the steps and conditions outlined in items from 5.3.7 above, including acknowledgment of the approval conditions.

5.4.6 Once the applicant has received the ED or NLRD variation approval notification, they must read and ensure they understand the approval memo and any associated conditions. Where required, they will be prompted to submit a declaration in GSafe, which will allow the dealing to fully be approved. Work may then commence in accordance with all approval conditions.

5.5 Conflict or Potential Conflict of Interest

When a person is assigned to a review panel and they believe there is, or may appear to be, a conflict of interest with regards to a project application they must declare the conflict of interest prior to, or at, the commencement of the review process, and remove themselves from the review.

Should it become apparent during the review of a project application that there is a conflict of interest and it has not been declared, the reviewer must declare the conflict of interest immediately to Compliance Coordinator in writing. The actions taken to manage the conflict of interest will be evaluated at the time the conflict is announced, with a restart of the review process being one of the options available.

5.6 Extension of Approved Dealings

The maximum time period for which a GMO dealing approval is granted is 5 years minus 1 day. If the initial approved project length is less than this, the dealing may be extended up to the maximum time period by following the instructions for variations described in Section 5.4. The extension may be approved by a Technical Review panel provided there are no other changes requested.

For DNIRs and DIRs the OGTR may grant an extension beyond the 5 year period. The initial steps to vary a DNIR or DIR are as described above in Section 5.4, *i.e.* it will go through an internal review prior to being submitted to the OGTR. When the variation application is submitted to the OGTR they will evaluate and risk assess the entire Licence and application within the time frames described in Item 5.3.6.

5.7 Final Report Declaration

At the conclusion of the project a final report declaration via GSafe is required to verify that all GMOs have either:

- Been destroyed, including information regarding how this was done, when and by whom; or
- Transferred to a new project application; or
- Transferred to another organisation (a copy of the other organisation's gene technology approval to be provided as evidence); or
- Are appropriately stored in accordance with legislative requirements and an approved storage application is in place.

If the Leader of the approved dealing is leaving the University and taking all their GMOs they are required to notify the UBC and complete a final report declaration for any current dealings.

6.0 Approval Conditions

A number of standard approval conditions will be placed on approved GMO project applications. Other conditions may be added to the approval depending on the nature of the project.

Typical approval conditions include:

6.1.1 GMO projects may be approved for a maximum five (5) year period minus 1 day. If further time is required to complete the work a new application is required.

6.1.2 All persons involved in a project, in particular those leading the project, must ensure that they read and understand the project approval conditions and requirements.

6.1.3 Approval of the project is strictly limited to the dealings outlined in the project approval memo or licence and no variations or modifications of the research project can be undertaken without prior written approval from the UBC or OGTR as required.

6.1.4 Activities must be contained within a facility and must not involve the intentional release of the GMO into the environment.

6.1.5 All persons undertaking any dealing involving GMOs must ensure that the required training requirements and induction(s) have been undertaken in accordance with the project, licence and/or facility conditions.

6.1.6 Facility work practices must comply with facility certification requirements at all times.

6.1.7 A GMO inventory must be kept and be readily retrievable at all times to account for the location of all GMOs.

6.1.8 GMO material storage records and arrangements must provide segregation, identification (including dealing identifier) and the easy retrieval of GMO material.

6.1.9 Storage of NLRD GMOs outside of a certified facility must only occur with written approval from the UBC and undertaken in accordance with the applicable OGTR guidelines.

6.1.10 The UBC must be notified in writing of any GMO material being transported external to the University prior to transport occurring, and be done in accordance with the applicable OGTR guidelines.

6.1.11 Disposal of GMOs and any item potentially contaminated with GMOs must be undertaken in accordance with the appropriate OGTR guidelines and relevant facility certification guidelines.

6.1.12 The GMO dealing must comply with other applicable legislative requirements *e.g. Biosecurity Act 2015*, the *Animal Care and Protection Act 2001 (QLD)*, and general health and safety obligations.

7.0 Record Management

The records of assessment (RoA) of NLRDs, *i.e.* the approved application and approval memo, must be kept for a minimum of 8 years after the date of assessment by the UBC. From late 2017 onwards these records will be stored within the GSafe. Prior records are held by Information Management. Every participant on an approved project will be able to view the approved version of the application when they log into GSafe.

8.0 Responsibilities

1. The UBC Chair, or in their absence, the Deputy Chair, is the CEO delegated signing authority for project applications involving DNIRs and DIRs for the University.
2. The UBC Chair, or in their absence, the Deputy Chair, is responsible for making a decision regarding the recommendation of a project application and is the delegated signing authority for recommended applications.
3. The UBC Chair may delegate the authority to submit DNIR and DIR applications and variations on behalf of the University to one or more person.
4. The Compliance Coordinator will coordinate the review of GMO applications submitted for review (including the flow of the information between applicants and the review panel) and provide to the UBC Secretary, on an annual basis, the relevant information for the annual report on NLRD Assessments to the Regulator.
5. The Compliance Coordinator will provide DNIR and DIR applications, signed by the project supervisor to an Authorised Person for final review, signing by the Chair and submission to the OGTR.
6. The Senior Manager, Health, Safety & Wellbeing will provide information to the UBC Secretary on approved EDs and NLRDs for noting by the UBC.
7. The relevant Authorised Person will advise the UBC Chair of the review panel's recommendation on DNIR and DIR project applications and coordinate the University's authorisation and submission to the OGTR.
8. As soon as practicable after the end of each financial year, and before the following 30 September, the UBC Secretary must submit to the Regulator, as part of the annual report, the record of NLRD Assessments in the form required by the Regulator.
9. UBC review panel members and any person who may be requested or required to undertake a project assessment are responsible for;
    a. provision of an expert review to assess and advise on the identification and management of risks associated with dealings with GMOs; and
    b. provision of a recommendation with respect to a submitted project application within the agreed timeframe.
10. A UBC member who has a conflict of interest must declare the conflict of interest prior to the commencement of any project review to consider that matter. If the UBC member does not have notice of the matter prior to the project review the member must declare the conflict of interest immediately upon becoming aware of it.
11. The Principal Researcher (or Course Convenor) has primary responsibility for project applications involving GMOs. The task of submitting the application to the UBC for review and approval can be delegated, however responsibility remains for accuracy of information provided and for undertaking the project in accordance with any conditions or requirements specified or imposed by either the OGTR or the UBC.

9.0 Appendix 1

Table 1. GMO application types and details of the UBC review process for each. ###: sequential number starting at 01 each year, YY: final two digits of the year in which it was submitted.

Dealing Type	**UBC Identifier Format**	**Scientific Panel**	**Technical Panel**	**Review Type**	**Review Round Length**	**Regulator Requirement**	**Declaration**
Exempt Dealing (ED)	ED/###/YY	2 Internal	1 Internal, 2 if Animals Used	Out of Session	7 working days/round	Make available to OGTR during an inspection.	×
Notifiable Low Risk Dealing (NLRD)	NLRD/###/YY	2 Internal, 1 External	1 Internal, 2 if Animals Used	Out of Session	7 working days/round	Provide list of approved dealings annually.	✓
Dealing Not Involving and Intentional Release (DNIR)	DNIR/##/YY	3 Internal, 1 External	1 Internal, 2 if Animals Used	Out of Session, Face to Face Panel	14 working days/round	Must be submitted to OGTR for Licence to be granted.	✓
Dealing Involving Intentional Release (DIR)	DIR/##/YY	3 Internal, 1 External	1 Internal, 2 if Animals Used	Out of Session, Face to Face Panel	TBA	Must be submitted to OGTR for Licence to be granted.	✓